VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **264745-2 (S)** **Related reports:** 264745-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
-0.6	M	31-Aug-2006	31-Aug-2006	0	09-Feb-2010	10-Feb-2010	ME	WAES0609USA02871B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0637F	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Gastroschisis

Symptom Text: Information has been received from a consumer's OB-GYN, for GARDASIL (Lot # 653937/0637F), a Pregnancy Registry product, concerning a baby boy. The boy's 15 years old mother with no known drug allergies, and with depression who on 31-AUG-2006 at 3:00 PM was vaccinated intramuscularly in the right deltoid with the first dose of with GARDASIL (Lot # 653937/0637F). Illnesses at time of vaccination included flu symptoms and a breast lump. Concomitant therapy included ZOLOFT. Other vaccinations given on 06-SEP-2006 included DTAP (unspecified). It was reported that the patient was aware that she was pregnant but did not disclose this information to her health care provider until after vaccination. Subsequently the patient delivered via vaginal delivery a "healthy baby boy but had gastroschisis". The baby was born on 07-APR-2007 and APGAR scores were 8 and 9 at one and five minutes, respectively. The nurse was unable to provide the infant's birth weight and indicated that infants born with this congenital anomaly are generally hospitalized for 12 weeks. The nurse could not confirm when and if this infant had been discharged from the hospital. The mother's experience has been captured in WAES #0609USA02871. The baby's experiences were previously reported in WAES #0609USA02871 on 22-AUG-2007. Additional information is not expected. The mother's experience has been captured in WAES #0609USA02871. The baby's experiences were previously reported in WAES #0609USA02871 on 22-AUG-2007.

Other Meds: Zoloft

Lab Data: Unknown

History:

Prex Illness: Flu symptoms; Breast lump; Depression

Prex Vax Illns:

Vaers Id: **285693-3 (S)** **Related reports:** 285693-1; 285693-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Jun-2007	30-Jun-2007	0	05-Jan-2010	06-Jan-2010	NJ		12-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	0	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Confusional state, Delusion, Derealisation, Disturbance in attention, Flight of ideas, Mania, Speech disorder

Symptom Text: Confusion,word usage problems, flight of ideas, lack of concentration,within 2 days total manic episode, delusions,did not realize we were her parents, etc.

Other Meds: Had never been on any medicines at any time

Lab Data: all physical tests possibe, hormonal, thyroid, etc. Blood work, brain scans

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **295242-2** **Related reports:** 295242-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Oct-2007	17-Oct-2007	0	11-Mar-2010	22-Mar-2010	--	200901323	22-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Encephalitis, Facial palsy, Hypoaesthesia, Hypoaesthesia facial, Hypoaesthesia oral

Symptom Text: This serious case was extracted from VAERS on 28 March 2009 (VAERS reference number 295242). A 13-year-old female patient with no reported medical history had received a first dose intramuscular injection of MENACTRA (lot number and site of administration not reported) and a second dose intramuscular injection of GARDASIL (HPV, manufacturer Merck, lot number and site of administration not reported) on 17 October 2007. On the day of vaccination (also reported as 28 October 2007), the patient complained of numbness to her hands and feet. She later developed numbness in her lower arms, lips and face. She was seen by a neurologist on 12 November 2007 and had been diagnosed with post infection "cerebellitis" and right Bell's Palsy and she was noted to be improving. Laboratory testing included CBC, Chem 16 and ESR; results were reported as lymph %51, alk phos 180 and ESR 2. According to the reporter, the current clinical events were not related to vaccination with GARDASIL. The onset date of 28 October 2007 was reported for the events of numbness to lower arms, lips and face; right Bell's Palsy, and post infection cerebellitis. The patient's recovery status was not reported.

Other Meds:

Lab Data: CBC, Chem 16 and ESR; lymph, %51, alk phos 180, ESR 2.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **295507-4 (S)** **Related reports:** 295507-1; 295507-2; 295507-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Jul-2007	07-Aug-2007	14	11-Mar-2010	15-Mar-2010	--	200901318	29-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Ataxia, Azotaemia, Clonus, Diplopia, Dysphagia, Eye movement disorder, Fall, Fatigue, Gait disturbance, IIIrd nerve paralysis, Intensive care, Muscular weakness, Pain, Renal disorder, Renal impairment, Strabismus

Symptom Text: This case was extracted from the VAERS database on 28 March 2009 (reference number 295507). A 12-year-old female patient received an intramuscular first dose of MENACTRA (lot not reported) and an intramuscular first dose of GARDASIL (Merck, lot not reported) on 24 July 2007. On approximately 07 August 2007, 14 days post-vaccination, the patient began developing diplopia, ataxia, and weakness in the extremities. She was seen by a physician on 13 August 2007 and noted to have an unsteady gait and abnormal eye movements. She had reportedly began "running into things and falling", with worsening weakness and pain. Physical exam was remarkable for decreased strength in the upper and lower extremities, 1-beat clonus bilaterally, cranial nerve III palsy, and right exotropia. MRI of the brain was markedly abnormal involving midbrain and base of brain. BUN and creatinine were increased. She was admitted to the PICU on 14 August 2007 after becoming increasingly more encephalopathic during admission. She developed deteriorating renal function/azotemia, which worsened following a CT with contrast. Treatment included intravenous and oral steroids, and she was discharged on hospital day 10 with aspiration precautions. Treatment included intravenous and oral steroids, and she was discharged on hospital day 10 with aspiration precautions. No formal discharge diagnosis was noted, but a diagnosis of acute disseminated encephalomyelitis was proposed following diagnostic studies. As of a follow-up phone call on 28 December 2007, the patient still had occasional double vision when tired. Other symptoms, including ataxia, dysphagia, and renal dysfunction, had resolved. Final outcome was not reported. Follow up information was received on 10 April 2009 from the Food and Drug Administration (FDA). Per the FDA, this case did not meet probable or confirmed ADEM case definition of diagnostic certainty for level 1 or 2. Documents held by sender: None.

Other Meds:

Lab Data: MRI of the brain was markedly abnormal involving midbrain and base of brain. BUN and creatinine were increased.

History: None reported.

Prex Illness:

Prex Vax Illns:

Vaers Id: **295876-3** **Related reports:** 295876-1; 295876-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		23-Sep-2009	24-Sep-2009	--	WAES0909USA02424	24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Economic problem, Mental disorder, Pain

Symptom Text: Information has been received from a lawsuit concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently the patient suffered damages including but not limited to seizures, pain and suffering, mental anguish and economic losses. At the time of the report, the patient continued to experience the residual effects of taking the product. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **305606-4** **Related reports:** 305606-1; 305606-2; 305606-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Nov-2007	01-Nov-2007	0	30-Sep-2009	01-Oct-2009	--	WAES0909USA04165	01-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abasia, Arthralgia, Gastrointestinal disorder, Loss of consciousness, Migraine, Monoplegia, Myalgia, Neuropathy peripheral, Rash, Skin papilloma, Sleep apnoea syndrome, Syncope, Visual field defect

Symptom Text: A consumer obtained the information from a news article that her daughter who in November 2007, was vaccinated with a dose of GARDASIL (lot number not provided). The patient was vaccinated the next two doses of GARDASIL on unspecified dates. The patient was constantly fainting. When she fainted, she lost her ability to walk. On approximately 15-SEP-2009, "just two days ago", the patient was found unconscious in the hall at school and was brought back by a paramedic. The patient was diagnosed with peripheral neuropathy in both feet, migraine headaches, fainting (syncope) and sleep apnea. The patient has lost peripheral vision in her left eye and reported that her joints and muscles hurt constantly. The patient also had gotten warts, rashes and digestive illnesses. The patient has not had a period since November of 2007. The patient's arm became paralyzed after her third shot. It was unknown if the patient sought medical attention. At the time of the report, the outcome of the event was unknown. Upon internal review, sleep apnea and lost peripheral vision in her left eye were determined to be other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **307394-6** **Related reports:** 307394-1; 307394-2; 307394-3; 307394-4; 307394-5

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		28-Oct-2009	29-Oct-2009	RI	WAES0910USA02713	30-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amyotrophic lateral sclerosis

Symptom Text: Information has been received from a physician who reported that a report was posted about two patients who developed amyotrophic lateral sclerosis 4 months after receiving their second dose of GARDASIL. At the time of the report, the patient's status was unknown. Attempts are being made to verify the existence of an identifiable patient and reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **307835-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Feb-2008	01-Feb-2008	0	17-Mar-2008	11-Apr-2008	TX	WAES0802USA06097	01-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Delivery, Drug exposure during pregnancy, Metrorrhagia, Muscle spasms, Pre-eclampsia

Symptom Text: Information has been received from a nurse concerning a 13 year old female who on 01-FEB-2008 was vaccinated with the first dose of Gardasil and is now pregnant. Concomitant therapy included MIRALAX. The patient is currently spotting and cramping which is relieved by rest. Medical attention was sought at the school nurse. Patient outcome is unknown. No product quality complaint was involved. Additional information has been requested. This is in follow-up to report (s) previously submitted on 3/14/2008. Additional information has been received from the physician who stated that the patient "had no complications from the vaccine" and she and the baby were fine. The physician reported that the patient was diagnosed with pre-eclampsia and delivered at about 30-32 weeks gestation by cesarean section. The physician also added the mother and the baby were both doing fine now. The mother was physically fine. The reporter also added that the baby had no anomalies "nothing untoward because of the vaccine". Upon internal review, pre-eclampsia and delivered at about 30-32 weeks gestation by cesarean section were considered to be Other Important Medical Events. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 1/12/2008)

Prex Vax Illns:

Vaers Id: **310953-2** **Related reports:** 310953-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-Aug-2007	Unknown		11-Mar-2010	18-Mar-2010	--	200901328	19-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blunted affect, Condition aggravated, Conversion disorder, Decreased eye contact, Dysphemia, Encephalopathy, Headache, Hypoaesthesia, Induration, Muscle twitching, Sensory loss, Speech disorder, Stress, Tremor, Vertigo

Symptom Text: A 13-year-old female patient received MENACTRA and GARDASIL (Merck); lot numbers not reported) on 20 August 2007. On an unreported date, she developed left-sided numbness, left hand, face, and leg tremors, twitching, periodic vertigo, headache, and her left arm was "hard". Upon examination she was noted to have blunted affect, poor eye contact, slow speech, and mild decreased sensation of the left upper extremity with normal strength, tone, and reflexes. She was seen in a neurology clinic from 20 January through 21 February 2008, and during that time her tremors increased and she had begun stuttering. An EEG was abnormal, with mild encephalopathy and abnormalities suggesting a risk for focal seizures. CBC, chemistry, UA, urine culture and sensitivity, monospot, and MRI of the brain and spine were all within normal limits. The final diagnosis was stress-induced conversion reaction. The patient was referred for counseling; outcome was not reported.

Other Meds:

Lab Data: An EEG was abnormal, with mild encephalopathy and abnormalities suggesting a risk for focal seizures. CBC, chemistry, UA, urine culture and sensitivity, monospot, and MRI of the brain and spine were all within normal limits.

History: None reported.

Prex Illness:

Prex Vax Illns:

Vaers Id: **312548-2** **Related reports:** 312548-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-Feb-2008	15-Mar-2008	16	17-Jul-2009	19-Aug-2009	VA	WAES0805USA00164	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pyrexia

Symptom Text: Information has been received from an office manager for the pregnancy registry for GARDASIL concerning a 20 year old female with no medical history and no known allergies who on 28-FEB-2008 was vaccinated with the second dose of GARDASIL (Lot # 655327/1287U). There was no concomitant medication. The reporter indicated that the patient was pregnant with an expected due date of 02-DEC-2008. Unknown medical attention was sought in the office. Patient outcome was unknown. No product quality complaint was involved. Follow up information received from a nurse revealed that the patient had a spontaneous vaginal birth on 25-NOV-2008 and delivered a healthy, normal, female weighing 7 pounds and 4 ounces. There were no prenatal complications. The only additional note was that of "maternal fever" in labor, with no further explanatory information. The patient was seen for her post partum visit and was fine. No further information is available.

Other Meds: None

Lab Data: Beta-human chorionic, 04/07/2008, posit

History:

Prex Illness: Pregnancy NCS (LMP - 3/15/2008)

Prex Vax Illns:

Vaers Id: **312938-2 (S)** **Related reports:** 312938-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		28-Aug-2009	31-Aug-2009	--	WAES0908USA03988	31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Back pain, Dizziness, Migraine

Symptom Text: Information has been reported in non medical media article that a 15 year old consumer and her mother reported that on an unknown date the patient was vaccinated with a first and second dose of GARDASIL. It was reported in the news media that after two doses, the vaccine knocked the patient "on her back for two months". It was also reported that the patient stated that though better now "I still have a lot of terrible migraine headaches and back pain, dizziness". The patient's mother also stated that: "That hits close to home in the sense of when your daughter's laying in a hospital's bed". It was not specified if the patient was hospitalized. Upon internal review "on her back for two months" was considered as disabling. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318483-2 (S)** **Related reports:** 318483-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-May-2007	24-Jun-2007	53	29-Jan-2010	01-Feb-2010	--	WAES0807USA05072	01-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Asthenia, Chest pain, Computerised tomogram, Delusion, Disorientation, Dizziness, Hot flush, Hyperhidrosis, Loss of consciousness, Malaise, Myalgia, Nausea, Syncope, Ultrasound scan, Visual impairment, X-ray

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act concerning a 15-year-old female with no known allergy nor illness, who on 02-MAY-2007 was vaccinated IM in her left arm with the second dose of GARDASIL vaccine (lot # 658094/0524U). Concomitant medication included albuterol. On 24-JUN-2007, the patient experienced lightheadedness, dizzy, seeing spots, abdominal pain, nausea and left upper quad pain. It was not reported whether medical attention was sought. In July of 2007 after the vaccination, she experienced all of these (lightheadedness, dizzy, seeing spots, abdominal pain, nausea and left upper quad pain) plus severe hot flushes, sweats, severe muscle pain and weakness, collapsing and passing out as well as chest pain. According to the report: "she was now sick on a monthly basis and her sickness usually last 7-8 days. She also becomes delusional at times and spacey." The report also stated: "Several different lab studies, ultra sounds, x-rays, CT scans and an appointment with the endocrinologist which didn't do us any good. She was a perfectly healthy kid until she received this vaccine." The original reporting source was not provided. The VAERS ID # is 318483. No further information is available. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to released met all release specifications. The lot met the requirements of the research center and was released.

Other Meds: albuterol

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320257-2** **Related reports:** 320257-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	28-Nov-2007	10-Dec-2007	12	26-Aug-2009	27-Aug-2009	PA		28-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthropathy, Burning sensation, Joint stiffness, Joint swelling, Oedema, Rheumatoid arthritis, Weight increased

Symptom Text: 3 weeks after the first vaccine I had gained 25 pounds in excess fluid on my joints. I had 3 hours + of morning stiffness, hot and red joints (predomint in my hands, wrists, toes, and ankles)- bilateral swelling. Severe edema, etc. I was treated with steroids and passed around as a mystery illness until almost 1 year later, where I was diagnosed with rheumatoid arthritis at the clinic. I am currently (and have been for a year) taking plaquenil, humira. I did take methotrexate for about 6 months, but it caused too much nausea.

Other Meds: nuva ring

Lab Data: elevated rheumatoid factor for the first 8 months following the first shot, now the level is normal, but I am still symtematic

History: allergic to sulfa drugs

Prex Illness: none

Prex Vax Illns:

Vaers Id: **321767-2 (S)** **Related reports:** 321767-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	01-May-2007	01-Jun-2007	31	25-Aug-2009	31-Aug-2009	IL		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Pancreatitis, Small intestine ulcer, Vaccine positive rechallenge

Symptom Text: Received 1st shot in May 2007. Shortly after started complaining of stomach pains. Pain lasted for several months. Pain stopped Jan. 2009. Received 2nd shot 1-28-08. Shortly after stomach pain returned. Was hospitalized 4-08 with pancreatitis. Found small intestinal ulcers 9-08. Still has continual pain with no known cause. Also has some knee pain.

Other Meds: No

Lab Data: Endoscopy/Colonoscopy; Pill cam endoscopy; Blood; Stool; Urine

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322400-3 (S)** **Related reports:** 322400-1; 322400-2; 322400-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-Jun-2007	22-Jun-2007	7	22-May-2009	26-May-2009	NY	WAES0905USA02258	31-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0469U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Angiogram, Computerised tomogram, Condition aggravated, Conversion disorder, Deafness, Echocardiogram, Electroencephalogram, Epistaxis, Gait disturbance, Lumbar puncture, Migraine, Muscular weakness, Myalgia, Nuclear magnetic resonance imaging, Nuclear magnetic resonance imaging brain, Palpitations, Regressive behaviour, Syncope, Vaginal odour

Symptom Text: Information has been received from a physician concerning a 21 year old female with partial hearing loss due to congenital sensory nerve damage, irritable bowel syndrome and gastrooesophageal reflux disease and a history of gastric ulcer perforation who was vaccinated IM with the first dose of GARDASIL, 0.5ml on 15-JUN-2007. There was no concomitant medication. Starting on 22-JUN-2007 the patient experienced migraine headaches and palpitations. In October 2007 the patient received her second IM dose of GARDASIL 0.5 ml, but has not had her third dose. In January 2008, the patient started having syncopal episodes and pseudoseizures. The patient, who was born with hearing loss due to sensory nerve damage, lost her remaining hearing in March 2008. Since the beginning of 2009, the patient had experienced episodes of behavioral regression as well as muscle pain and weakness. Due to the muscle weakness, the patient had limited ambulation. Since April 2009 the patient had recurrent nosebleeds. The patient has required multiple hospitalizations and office visits. The patient had MRI/MRA of head, CT Scan/CTA of head, EEG, echocardiogram, lumbar puncture and angiogram performed (results not reported). At the time of the report (on 18-MAY-2009) the patient was not recovered. The reporter considered the events to be disabling. Additional information has been requested. 7/9/09 Medical records received DOS 6/5/07 to 10/5/07. Patient complains of vaginal odor.

Other Meds: None

Lab Data: Unknown. 7/9/09 Medical records received DOS 6/5/07 to 10/5/07. LABS and Diagnostics: All pending. PAP, GC, Vaginitis Panel, Thyroid panel, Glucose, endocrine studies.

History: Gastric ulcer perforation

Prex Illness: Nerve damage; Irritable bowel syndrome; Partial hearing loss; Gastrooesophageal reflux disease

Prex Vax Illns:

Vaers Id: **322400-4 (S)** **Related reports:** 322400-1; 322400-2; 322400-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-Oct-2007	17-Oct-2007	2	25-Jun-2009	26-Jun-2009	NY	WAES0906USA03810	01-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0742U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Alopecia, Autism spectrum disorder, Blood testosterone increased, Chest pain, Convulsion, Deafness, Emotional disorder, Epistaxis, Flushing, Foaming at mouth, Gastrooesophageal reflux disease, Hallucination, Irritable bowel syndrome, Malaise, Migraine, Nausea, Oedema peripheral, Pain, Paraesthesia, Regressive behaviour, Syncope, Tonic clonic movements, Tremor, Weight increased, Wheelchair user

Symptom Text: Information has been received from a consumer concerning her 21 year old daughter with "immune deficiency runs in family" who on 15-JUN-2007 and on 15-OCT-2007 was vaccinated with first dose (route not reported, lot number 0469U) and second dose (route not reported, lot number 654539/0742U) respectively of GARDASIL. The patient's mother reported that her daughter has been severely ill since receiving the second dose of the vaccine. It was reported that on 17-OCT-2007, the patient's symptoms started with chest pain, migraines, fainting, facial flushing, seizure and nausea. It was reported that she now has emotional regression and spectrum disorder, swelling of legs and feet, inability to walk, pain all over her body, felt "shocks to her brain", clonic tonic symptoms, hair loss, foaming from mouth, nosebleeds, hallucinations, hearing loss, weight gain, shaking like PARKINSON's disease, acid reflux, irritable bowel and high testosterone levels. She reported that her daughter was gone to the hospital over fifteen times and had been admitted nine times to three different hospitals. The patient has been seen by many doctors including neurologist and neuropsychiatrist. She had also had alternative medicine treatments including detoxification, cranial massage and reflexology. It was reported that she was now using a wheelchair and needed to be carried. Lab tests performed included lumbar puncture, cerebral angiogram, EEG and many others which were all negative. As of 19-JUN-2009, the patient had not recovered from the events. Additional information has been requested. 02/01/2010 Seizures, syncope, numbness, tingling, profound deafness, hair loss, bloddy nose, chronic pain, fatigue, shortness of breath, regression occassional inability to walk, legs give out, brain fog, confusion.

Other Meds: Unknown

Lab Data: spinal tap, Negative; cerebral angiography, Negative; electroencephalography, Negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323863-2 (S)** **Related reports:** 323863-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jun-2008	11-Aug-2008	55	15-Jun-2009	15-Jul-2009	--	WAES0905USA00591	26-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Blood product transfusion, Depressed level of consciousness, Electroencephalogram, Fatigue, Gait disturbance, Guillain-Barre syndrome, Headache, Lumbar puncture, Myalgia, Nausea, Nuclear magnetic resonance imaging, Ultrasound scan

Symptom Text: Information has been received from a Registered Nurse (R.N.) concerning a 19 year old female who on 17-JUN-2008 was vaccinated with the first 0.5 ml dose of GARDASIL (lot number not provided). Concomitant therapy included MENACTRA. On 11-AUG-2008 the patient experienced fatigue and walking problem. The patient was hospitalized from 21-AUG-2008 to 24-AUG-2008 and on 24-AUG-2008 the patient was diagnosed with Guillain Barre syndrome. At the time of reporting the patient was not recovered. Follow up information was received from a Registered Nurse (R.N.) on 06-MAY-2009 via telephone provided the patient's name and date of birth. She confirmed that the patient received the first and only dose of GARDASIL on 17-JUN-2008 (lot# 660391/0063X) along with concomitant vaccine MENACTRA. The AE onset date was 11-AUG-2008 around 1:00 am. She went to the emergency room via ambulance with intolerable head and muscle pain, difficulty walking, nausea, and change of responsiveness. At the emergency room she was told that it was "viral" and was sent home. On 21-AUG-2008 she had a follow up doctor visit and she went into another hospital, while there she was referred to a neurologist. A CAT scan (negative results), EEG, Spinal Tap, MRI, and ultrasound of her bladder were performed. She was diagnosed with Guillain Barre syndrome. She was hospitalized from 21-AUG-2008 to 24-AUG-2008. She received globulin intravenously, pain medication, and physical therapy. Prior to this the patient had a baby. It was reported that as of 17-MAR-2009 the patient was still recovering and still going to physical therapy. Additional information has been requested.

Other Meds:

Lab Data: computed axial, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324299-2** **Related reports:** 324299-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Jul-2008	15-Jul-2008	0	28-May-2009	29-May-2009	NY	WAES0809USA00278	29-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0085X		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for VARIVAX, a pregnancy registry product, concerning a 15 year old female patient who on 15-JUL-2008 was vaccinated with a dose of VARIVAX (lot #659844/0085X) when she was pregnant. That same day, she was vaccinated with hepatitis A virus vaccine (unspecified) and MENACTRA. On 26-AUG-2008, the patient had a urine pregnancy test done confirming the pregnancy. No adverse event was reported. The patient sought medical attention informing staff she missed her period after she was vaccinated. Follow up information received on 20-MAY-2009 from the physician stated that the patient received a dose of VARIVAX, GARDASIL, and MENACTRA at the same medical center. Two weeks after the pregnancy was confirmed the patient had an elective termination of pregnancy. At the time of reporting the patient's outcome was unknown. Upon internal review elective termination was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: urine beta-human, 08/26/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **327120-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	17-Sep-2008	18-Sep-2008	1	06-Oct-2008	15-Oct-2008	MI	MI2008022	03-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2844AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0245U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site mass, Injection site pain, Musculoskeletal discomfort, Pain in extremity, Pharyngolaryngeal pain

Symptom Text: Soreness right arm injection site and redness with lump. Lump above collar bone inner aspect near neck. Soreness of right arm. C/O discomfort right side of neck when move head. Advised to consult with healthcare provider - provided with resources. Had viral infection 6 weeks prior to moving to another city. Has been in city for 3 weeks. Complains now of sore throat.

Other Meds:

Lab Data:

History: Poly Cystic ovarian syndrome; history of migraine; PCN; Ceclor

Prex Illness: Sinus drainage

Prex Vax Illns:

Vaers Id: **329280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Jan-2008	09-Apr-2008	98	17-Oct-2008	11-Feb-2009	NY	WAES0809USA00346	22-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration, Ovarian cyst

Symptom Text: Initial and follow-up information has been received from a licensed practical nurse for the pregnancy registry GARADASIL concerning a 14 year old white female with asthma and no allergies, no previous pregnancies and a history of appendicectomy who on 23-MAY-2007 was vaccinated with the first dose of GARDASIL, IM 0.5 mL (lot # 654535/0960F). On 02-JAN-2008 the patient was vaccinated with the second dose of GARDASIL, IM 0.5 mL (lot # 659055/1522U). On 09-APR-2008, the patient was noted to have a right ovarian cyst. On 07-MAY-2008 the patient vaccinated with the third dose of GARDASIL, IM 0.5 mL (lot # 659964/1978U). Concomitant therapy included FLOVENT and albuterol. The patient's last menstrual period was 17-MAY-2008. The estimated due date is 21-FEB-2009. The patient had a positive urine pregnancy test on 14-AUG-2008. The ultrasound was performed on 26-AUG-2008 for dates with the results of 11 week 2 day fetus. No problems reported. The patient sought medical attention in the office visit. Additional information has been requested. This is in follow-up to report (s) previously submitted on 10/14/2008; 7/8/2009. Follow-up information was received from the LPN via a pregnancy questionnaire. Other medication used during pregnancy included TYLENOL for headache as needed. On 17-MAR-2009 the patient delivered a normal male baby weighing 7 pounds 14 ounces with apgar score 8/9 at 40 weeks and 2 days. The length of the baby was 20.25 inches and head circumference was 33.5 cm. There were no congenital anomalies or other complications or abnormalities. There was no complication during pregnancy and labor/delivery. There was no diagnostic test during pregnancy. Follow-up information was received from a physician via pediatric medical records. The baby with no known drug allergies was treated with erythromycin (05-APR-2009) (reason not reported). On 23-MAR-2009, the baby was seen by the physician with the assessment of a well physical examination. On 30-MAR-2009 the baby was seen with results of weight normal an

Other Meds: albuterol; FLOVENT

Lab Data: ultrasound, 08/26/08, 11 week 2 day fetus; urine beta-human, 08/14/08, positive

History: Appendicectomy

Prex Illness: Pregnancy NOS (LMP = 5/17/2008); Asthma

Prex Vax Illns:

Vaers Id: **334285-2 (S)** **Related reports:** 334285-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Aug-2008	08-Sep-2008	17	03-Nov-2009	04-Nov-2009	TX	TX090051PU	04-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2662AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0507X	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Balance disorder, Gait disturbance, Sensory loss

Symptom Text: RECEIVED 8/22/08 TWO WEEKS AFTER RECEIVING HPV#2 AND MENACTRA (9/8/08)SYMPTOMS CONSISTED OF LOSS OF SENSATION IN FEET, LOSS OF BALANCE DUE TO NO FEELING IN FEET, WALKS ONLY WITH ASSISTANCE. 1/29/2010 I know that within a few months after these vaccines were administered she couldn't walk and was going through testing at hospital.

Other Meds: NONE

Lab Data: CAT SCANS, SPINAL TAP, NERVE INDUCTION TESTS

History: ALLERGIC TO TREE POLLEN

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **335340-3 (S)** **Related reports:** 335340-1; 335340-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	15-Jul-2008	10-Nov-2008	118	21-Aug-2009	25-Aug-2009	NJ		26-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT B-cell lymphoma, Chemotherapy, Lymphadenopathy, Mediastinal mass, Neck mass, Non-Hodgkins lymphoma

Symptom Text: I received my first dose of Gardasil in July 2008 and my second dose in September 2008. I was diagnosed with a primary mediastinal B cell lymphoma (non-Hodgkin's) after feeling an enlarged supraclavicular lymph node in November 2008. CT/PET scan results showed a mass in my mediastinum as well as in my neck. I received 5 cyles of chemotherapy with cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, and rituxan, as well as prophylactic intraspinal chemotherapy. I was declared cancer-free in February 2009 and am currently in remission.

Other Meds: None at the time

Lab Data: All lab values were normal prior to chemotherapy.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **335410-2** **Related reports:** 335410-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Aug-2007	01-Nov-2007	92	17-Aug-2009	18-Aug-2009	GA	WAES0908USA01127	03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cancer in remission, Chemotherapy, Chest X-ray, Computerised tomogram, Fatigue, Lymphadenopathy, Migraine, Non-Hodgkins lymphoma, Pain, Positron emission tomogram, Pruritus generalised

Symptom Text: Information has been received from a consumer concerning a her 19 year old daughter with pertinent medical history reported as none and drug reactions or allergies reported as none who in January or February 2007, was vaccinated with a first dose of GARDASIL (lot # not reported). In April 2007 she received second dose of GARDASIL (lot # not reported). In August 2007 she received third dose of GARDASIL (lot # not reported). In November 2007 after vaccination with GARDASIL the patient developed non-Hodgkin's lymphoma. The first symptoms were itching all over her body, swollen lymph nodes and fatigue. She had 3A nodular sclerosing lymphoma. She had undergone 6 cycles of chemotherapy in 2008. At the time on the report on 07-AUG-2009 she was currently in remission. Upon internal review non-Hodgkin's lymphoma was determined to be an other important medical event. Follow up information has been received via telephone call from a nurse who refused to give any information concerning the patient without written authorization from the patient. Also the nurse stated that the patient received GARDASIL vaccinations at another physician's office. All telephone attempts to obtain follow up information have been unsuccessful. Additional information has been requested. 02/01/2010 Follow-up: Currently in remission. Requires regular CT, PET and chest x-rays for the next for years. She has recently had sever migraines and this pain.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **337242-2 (D)** **Related reports:** 337242-1; 337242-3; 337242-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	15-Nov-2008		07-Jul-2009	08-Jul-2009	--	WAES0906USA05777	08-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: It was reported from an article published on 29-JUN-2009 that a 20 year old patient was vaccinated with a dose of GARDASIL. On 15-NOV-2008 the patient deceased due to undetermined cause. This is one of several reports received from the same source. Attempts are being made to verify the existence of an identifiable patient and reporter.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **337242-3 (D)** **Related reports:** 337242-1; 337242-2; 337242-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Sep-2008	01-Sep-2008	0	06-Jul-2009	07-Jul-2009	--	WAES0906USA05351	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Abdominal pain upper, Autopsy, Death, Migraine

Symptom Text: Information has been received from a consumer, via a transcript of TV program concerning her 20 year old daughter who in September 2008 was vaccinated with GARDASIL (lot# not reported). The mother stated that almost immediately after receiving the vaccine, the patient suffered "unusual symptoms". In November 2008, two months later, the patient died without any apparent reason. The mother reported the autopsy revealed an "undetermined cause of death". The mother stated that her daughter was complaining of having migraine headaches and she had severe stomach pains the night before she passed away. The mother suspected her daughter's death as a result of GARDASIL. No further information is available at this time.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **337242-4 (D)** **Related reports:** 337242-1; 337242-2; 337242-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		19-May-2009	20-May-2009	--	WAES0905USA01652	06-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Death

Symptom Text: Information has been received from the office receptionist concerning her friend's girlfriend, an around 20 or 21 years old female, who was vaccinated via injection route with a dose of GARDASIL. Subsequently, the patient had a seizure and died. The patient sought unspecified medical attention. Seizure was considered to be immediately life-threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **337797-3 (D)** **Related reports:** 337797-1; 337797-2; 337797-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	31-Aug-2007		09-Jul-2009	10-Jul-2009	--	WAES0906USA05773	10-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death, Epistaxis, Feeling cold

Symptom Text: Information has been received from an article published on 29-JUN-2009 concerning an 18 years old female who was vaccinated with a dose of GARDASIL. On 31-AUG-2007 the patient died in her sleep after a quiet night of dinner and videos with her family. When her mother found her in bed, her body was cold and blood was puddling from her nose. The death reason was unknown. This is one of several reports received from the same source. Attempts are being made to verify the existence of an identifiable patient and reporter. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **337797-4 (D)** **Related reports:** 337797-1; 337797-2; 337797-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		22-Mar-2010	23-Mar-2010	--	WAES1003USA02416	23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Cardiomegaly, Death, Ventricular arrhythmia

Symptom Text: Information has been received from a consumer through an article on the internet concerning an 18 year old female who on an unspecified date was vaccinated with the dose of GARDASIL. On an unspecified date the patient died. The autopsy was performed and it was revealed that there was biventricular cardiomegaly, transmural replacement of myocytes by fibro-fatty tissue in the right ventricular wall and also diffuse variable myocyte hypertrophy. The arrhythmogenic right ventricular dysplasia (ARVD) was reported as a possible diagnosis. It was stated that because of the extensive tissue degeneration that had occurred prior to autopsy, some of these diagnostic findings could not be definitely identified. The cause of death was unspecified. This is one of several cases from the same source. Additional information has been requested.

Other Meds: unknown

Lab Data: unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **337805-2** **Related reports:** 337805-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Oct-2008	14-Oct-2008	0	17-Jul-2009	19-Aug-2009	NY	WAES0906USA02071	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain, No reaction on previous exposure to drug, Pain, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 13-year-old female with no medical history or allergies who on 14-OCT-2008 was vaccinated with the first dose of GARDASIL (Lot# 661044/0548X) 0.5ml. There were no concomitant medications. Patient didn't experience an AE after first dose. On 16-DEC-2008 the patient received the second dose of GARDASIL (Lot# 661764/0650X) 0.5ml. Subsequently, the patient developed pain at the injection site. The patient was recovered in January 2009. Additional information provided from a nurse indicated that the patient received her first dose of GARDASIL (Lot# 661044/0548X) 0.5ml on 14-OCT-2008. Following that injection she experienced "soreness to the touch" for 2 months (injection site reaction). The patient received her second dose of GARDASIL (Lot# 661764/0650X) 0.5ml on 17-DEC-2008. Right after the injection the patient experienced "shooting pains from the injection site to her fingertips". This had continued for several months. The patient was currently stating that the "shooting pain" has resolved, but she is not able to keep her arm raised because it bothers her. "It feels weird." The example the nurse provided is "she can not keep her arm raised while she is in school." The patient had sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **338247-3 (S)** **Related reports:** 338247-1; 338247-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Jan-2007	16-Jul-2007	174	28-Sep-2009	29-Sep-2009	--	WAES0902USA02812	24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0961F	0	Unknown	Intramuscular	
	HEPA	MERCK & CO. INC.	1209F	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2107AA	0	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Alopecia, Chest X-ray, Contusion, Diarrhoea, Dyspnoea, Ear infection, Influenza like illness, Nasopharyngitis, Pneumonia, Pyrexia, Sinusitis, Vomiting

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 17 year old female with an allergy to amoxicillin and AUGMENTIN who on 23-JAN-2007 was vaccinated intramuscularly with a first dose of GARDASIL (lot # 654389/0961F). Suspect therapy given intramuscularly included a first dose of VAQTA (lot #656495/1209F). Other concomitant therapy included a first dose of MENACTRA (lot # U2107AA) vaccinated intramuscularly on 23-JAN-2007. On 16-JUL-2007 the patient developed severe case of pneumonia with fever, no cough or cold prior. The patient was sent to hospital for chest X-ray where she was given inhalation therapy and prescribed cefdinir (300 mg) and albuterol (90 mg). In the evening of 16-JUL-2007, the patient went to emergency room when she couldn't breath. The patient received inhalation therapy and Z-PAK. On 18-JUL-2007 the patient was checked at doctor's office for improvement. On 19-JUL-2007 the patient was given additional albuterol (0.83 mg) and told to use one vial every 4 hours. It was reported that in July 2007, the patient was given refill of Z-PAK. On approximately 07-SEP-2007 the patient experienced fever. On 28-SEP-2007 the patient experienced sinus infection and was prescribed Z-PAK. It was also reported that in September 2007, the patient began losing substantial amounts of hair that continued for approximately 4 months. On 07-MAR-2008 the patient was seen for ear and sinus infection and fever and was prescribed Z-PAK. On 19-DEC-2008 the patient developed flu-like symptoms with vomiting, diarrhea and fever. The patient was given PHENERGAN (25 mg) and was sent to hospital when vomiting continued. The patient was given 3 bags of IV fluid and treated for vomiting and diarrhea. On 20-JAN-2009 the patient developed cold symptoms and fever. It was also reported that the patient had chronic bruising. Alopecia, contusion, diarrhoea, ear infection, influenza like illness, nasopharyngitis, pneumonia, pyrexia, respiratory arrest, sinu

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **338306-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Jun-2008	09-Oct-2008	104	26-Jan-2009	04-Feb-2009	NH		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB137AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0063X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling, Urticaria

Symptom Text: W/ 1st dose broke out in hives, w/2nd dose lips swelled as well as mouth.

Other Meds: Orthocyclin

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **338733-2 (S)** **Related reports:** 338733-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		23-Sep-2009	24-Sep-2009	NY	WAES0909USA02817	25-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Autoimmune thyroiditis, Convulsion, Electroencephalogram, Encephalitis, Endotracheal intubation, Laboratory test, Lumbar puncture, Respiratory arrest, Weight increased

Symptom Text: Information has been received from a nurse concerning a 17 year old female with no medical history or drug allergies, who over a year ago was vaccinated with a 0.5 mL second dose of GARDASIL. Two months later the patient started experiencing "major seizures". With her first seizure she went to the emergency room and later she was diagnosed with Hashimoto's encephalitis. The nurse mentioned that the patient was hospitalized and intubated twice because the seizures would cause her to go into respiratory arrest. She was placed on steroids as well as other medications (manufacturers unspecified) and steroids caused her to gain weight. The patient had a series of spinal taps, electroencephalographies, and other unspecified laboratory tests done. Therapy with GARDASIL was discontinued. At the time of this report the patient had not recovered. Hashimoto's encephalitis, gain weight and respiratory arrest were considered to be immediately life-threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **339375-2 (S)** **Related reports:** 339375-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	15-Jan-2009	28-Jan-2009	13	10-Dec-2009	11-Dec-2009	--	WAES0903USA04975	05-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0719X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Areflexia, Asthenia, Ataxia, Blood product transfusion, Dizziness, Guillain-Barre syndrome, Headache, Vertigo, Vomiting

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 15-JAN-2009, a 10 year old female with allergy to AMPICILLIN SULBACTAM was vaccinated IM into the right arm with the first dose of GARDASIL (lot # 0719X). There was no concomitant therapy. There was no preexisting illness. Thirteen days later on 28-JAN-2009 and for 3 days the patient had vomit, dizziness and cephalgia, later vertiginous sensation. On 31-JAN-2009, the patient presented a frank ataxia gait and progressive loss of strength in lower and upper extremities almost totally in the following 3 days with loss of osteotendinous reflexes. They had taken a normal brain computed axial tomography (CT) scan, a normal magnetic resonance imaging (MRI) and nerve conduction studies compatible with GBS. She started treatment with immunoglobulin with a response in 72 hours and almost total recovery of the motor function. Vertiginous felling and cephalgia still persisted. The listing indicated that one or more of the events required hospitalization, was considered to be immediately life-threatening. No further information is available. The original reporting source was not provided. The VAERS ID # is 339375. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released.

Other Meds: None

Lab Data: nerve conduction study, compatible with GUILLAIN-BARRE Syndrome; head computed axial, normal; magnetic resonance, normal

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **339421-2** **Related reports:** 339421-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Apr-2008	22-Apr-2008	0	02-Jul-2009	06-Jul-2009	CA	WAES0804USA06217	06-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arrested labour, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse and a doctor for the Pregnancy Registry for GARDASIL regarding a 15 year old female with of depression and stress gastritis (no medication prescribed) who on 22-APR-2008 was vaccinated intramuscularly with her first dose of GARDASIL (Lot # and site not reported). Concomitant therapy included VAQTA (Lot, site and route not reported). Other concomitant therapy included MENACTRA and Tdap (unspecified). Later on the evening of 22-APR-2008 the patient had a urine pregnancy test which was positive (not further specified). On 24-APR-2008, the patient returned to the office and a urine pregnancy test was performed which was positive (LMP "late February 2008"). No adverse effects were reported. The patient outcome was not reported. No additional information was provided. Follow-up information was received from a charge nurse who reported the patient delivered a male baby on 16-NOV-2008, at 38+1 weeks gestation. The patient was in labor, but experienced an "arrest of descent" in second stage, with a failed attempt at a vacuum delivery, and ultimately had a cesarean delivery. The baby weighed 6LBS 15oz. The baby was healthy and didn't have any problems. Upon internal review, arrest of descent was determined to be an other important medical events. No additional information was expected.

Other Meds:

Lab Data: Urine beta-human, 04/22/08, positive; Urine beta-human, 04/24/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 2/25/2008); Depression; Gastritis

Prex Vax Illns:

Vaers Id: **339652-2 (S)** **Related reports:** 339652-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jan-2009	02-Feb-2009	31	29-Aug-2009	03-Sep-2009	MO		03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	DON'T KNOW	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Chills, Convulsion, Dyskinesia, Dyspnoea, Gaze palsy, Headache, Joint lock, Muscle spasms, Muscle twitching, Musculoskeletal pain, Nervous system disorder, Opisthotonus, Ovarian cyst, Paraesthesia, Screaming, Speech disorder, Throat tightness, Tremor

Symptom Text: Reported once to Vaers, after first hospitalization. #E-28199 02/16/2009. My daughter continues having the violent seizure like episodes. Severe muscle spasms in her low back, making her fold backward, screaming in pain. Was hospitalized again on 4/02 through 4/05, again on 4/12 through 4/14. Her seizure episodes continued to get worse, even at times making her struggle for air. Felt like her throat was closing. Still having headaches. We then went to Mayo Clinic in MN, they slowly removed her from her medicines, she continued to have the episodes, but frequency was slowing down. Her eyes would also roll back into her head, and her speaking became "jibberish" while she was having the episodes. She also started complaining of stabbing pains in her lower stomach. That turned out to be an Ovarian Cyst. She was in the ER 3 times, after initial vaers report, 2 via ambulance. 6/01/2009, things seem to start getting better, episodes are limited to when she goes to bed, and drifts off to sleep. Her muscles twitch, jerk, and seem to have a mind of their own. She does not have control of her body, her muscles do. Still having headaches. 8/29/2009, things are mellowing out from 2/2009, but she still has neurological problems. Her head and neck twitch together, eyes roll back, electric volts feel like they go through her body, she shivers and it travels through her body, hands fold in, arms & legs shake uncontrollably. Her hips lock up, she cannot move, it hurts her very bad. It lasts from 7-10 minutes. Sometimes her arm just starts moving in all directions, she cannot stop it, today, it twisted itself so bad that her elbow, shoulder and wrist are very sore. It is the strangiest thing I have ever seen. The muscles have a mind of their own~ that is the only way I know how to explain it.

Other Meds: Oral Contraceptives

Lab Data: The hospital did tons of testing, blood, ua, bonescan, x-rays, cat scan, EEG, EKG, with video. PT

History: Allergic to Penicillin. Seasonal allergies

Prex Illness: none

Prex Vax Illns:

Vaers Id: **340758-2** **Related reports:** 340758-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Aug-2008	Unknown		25-Jun-2009	07-Jul-2009	AR	AR0927	04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2617AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0843X	1	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2997AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Chest pain, Depression, Headache, Mood swings, Palpitations, Pyrexia

Symptom Text: Mother reports approx. 3wks after the injection, that her daughter with complaint of increase depression, mood swings, headache, stomach pain and developed chest pain in Jan 2009. Went to Emergency Room in 8/13/08. May 8, 2009 with chest pain and heart racing. Fever. 104 still.

Other Meds: none

Lab Data: EKG on 5/8/09

History: none

Prex Illness: none

Prex Vax Illns: ~HPV (no brand name)~2~12.00~Patient

Vaers Id: **340882-3 (S)** **Related reports:** 340882-1; 340882-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Mar-2007	13-Mar-2009	731	11-Jun-2009	15-Jun-2009	NV		15-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0263U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Alopecia, Arrhythmia, Arthralgia, Asthenia, Blood pressure decreased, Body temperature decreased, Cardiovascular insufficiency, Coeliac disease, Constipation, Dizziness, Face oedema, Fatigue, Feeling abnormal, Headache, Heart rate decreased, Hypoaesthesia, Musculoskeletal stiffness, Nausea, Pain in extremity, Paraesthesia, Syncope, Tinnitus

Symptom Text: 2007-2009 - Light-headed/dizziness/pain in extremities/headache/nausea- ringing in ears/numbness/tingling/weakness/chronic fatigue-joint pain/abdominal pain/ chronic constipation/hair loss/facial edema/heart arrythmia/gluten intolerance/brain fog/collapsed 3X/stiffness/low body temperature/low heart rate/low blood pressure/poor circulation. Treatment: Detox therapy/colon hydrotherapy/supplementation and digestive aid.

Other Meds: None

Lab Data: Diagnosis: Thrombocytopenia/Chronic hypothermia/hypothyroidism/ammenorrhea/HCV pancytopenia/gastrointestinal disorder/ hormonal P.V. autoimmune disease imbalance.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **342045-2 (S)** **Related reports:** 342045-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	18-Oct-2007	18-Oct-2007	0	19-May-2009	20-May-2009	--	WAES0904USA01472	20-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TD	UNKNOWN MANUFACTURER	C2778AP		Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	500487P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1265U	0	Left arm	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Asthma, Biopsy skin, Computerised tomogram, Hyperhidrosis, Lethargy, Myalgia, Ovarian cyst ruptured, Pyrexia, Scar, Skin disorder, Skin lesion, Vertigo

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 13 year old very healthy and athletic female patient, allergic to the fruit formula given before having a CAT scan, was vaccinated in the left arm with the first dose of GARDASIL (Lot # 659435/1265U). Concomitantly, the first dose of influenza virus vaccine (unspecified) (manufacturer unknown) (Lot # 500487P) was given. It was reported that the patient experienced fever, severe abdominal pain and muscle aches. The patient was lethargic and had asthma. The patient also developed skin indentations (tissue break down up underneath the skin). The indentations were circular in size, starting around the injection site and had spread throughout entire body. A specialist stated that had never seen anything like it. The patient was referred for further testing. The indentations were not going away but permanently scarring the patient. The patient was also experiencing vertigo. Records received on 23-MAR-2009 from date of Service of 10-NOV-2008 presented a patient complaining of lesions to trunk and extremities. Records received on 30-MAR-2009 from Emergency Department visit on 02-NOV-2008 showed a patient complaining of abdominal pain and a diagnosis of ruptured ovarian cyst. Doctor's office records showed two other shots of Td adult vaccine given on 17-OCT-2008 (Lot # C2778AP) and also MONOTZ (Lot # U2426AA) given on 18-OCT-2007. Several biopsies were performed by two dermatologist (specialist) and regular dermatologist with unreported results. The patient did several regular doctor visits. An ultrasound and CAT scan of abdomen-biopsy were performed, which records were received on 23-MAR-2009, with unreported results. The listing indicated that one or more of the events required hospitalization. No further information is available. The original reporting source was not provided. The VAERS ID # 342045. Follow up information was received on 01-MAY-2009 via a senator's office, from a constit

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Contrast media allergy

Prex Vax Illns:

Vaers Id: **342159-2** **Related reports:** 342159-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2009	02-Jul-2009	1	21-Aug-2009	01-Sep-2009	PA		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Nausea

Symptom Text: Severe joint pain/nauseated/fatigue for weeks after shot. ADVIL or NAPROXYN to make comfortable.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **342520-3 (S)** **Related reports:** 342520-1; 342520-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-May-2007	01-Sep-2007	100	18-Jun-2009	19-Jun-2009	NC	WAES0906USA01931	19-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0186U	0	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	0001U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Burning sensation, Chest pain, Conversion disorder, Convulsion, Fatigue, Gallbladder operation, Headache, Heart rate increased, Hypotension, Inappropriate schedule of drug administration, Ovulation pain, Pain in extremity, Peripheral coldness, Syncope, Vaccine positive rechallenge, Vomiting

Symptom Text: Initial information has been received from a consumer concerning her 13 year old daughter who in May 2007 was vaccinated with the first dose of GARDASIL (lot # 655618/0186U) along with HAVRIX. Then about four months after the first dose in approximately September 2007 she experienced abdominal pain and soreness in the arm. Then On 24-JUN-2008, the patient was vaccinated with the second dose of GARDASIL (lot # 660555/0279X) along with HAVRIX and about four months after receiving the second dose in approximately October 2008 the patient collapsed on the basketball court with abdominal pain and chest pain which kept on getting worse. Then she received her third dose of GARDASIL (lot # 661044/0548X) along with MENGITIS (manufacturer unspecified) and HAVRIX and was experiencing abdominal pain, low blood pressure, high heart rate, legs feet and stomach felt like they were burning, but were cold to the touch and she had seizure like symptoms, fatigue and throwing up bile. The consumer reported that the patient has been in hospital from October, 2008 till March, 2009, went to the emergency room 8 times and was in the hospital for 25 days. The consumer also reported that after receiving the third dose of GARDASIL the patient had her gall bladder removed and was hospitalized for four days. Consumer reported that the patient has had many test done, which came back negative, and she was still experiencing abdominal pains. No further AE information provided. The consumer had completed the online document on the MERCK VAERS website. She provided reference # E28764. Follow up information has been received from a physician concerning the 13 year old female patient with a history of attention deficit disorder who on 24-MAY-2007 was vaccinated with the first dose of GARDASIL (lot # 655618/0186U) and concomitantly received the first dose of HAVRIX (lot # 0001U) (previously reported as Hep A). On 24-JUN-2008, the patient was vaccinated with the second dose of GARDASIL (lot # 660555/0279X) and concomitantly received the second dose o

Other Meds:

Lab Data: pelvic ultrasound, normal; abdominal computed, 09/10/08, normal; magnetic resonance, 11/20/08, magnetic resonance imaging brain normal; electroencephalography, 05/09/09, EEG kidneys were "OK"

History: Attention deficit disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: **343340-2** **Related reports:** 343340-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	23-Mar-2009	01-Apr-2009	9	04-Aug-2009	05-Aug-2009	NY	WAES0907USA05389	05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female who on 23-MAR-2009 was vaccinated with the second dose of GARDASIL (lot# 661703/0651X). On 01-APR-2009 the patient was diagnosed with BELLS palsy after the second dose of vaccination. The patient was sent to the emergency room but was not admitted. The patient is now being treated by a neurologist. At the time of the report, the patient had not recovered. Upon internal review, the BELLS palsy was considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343494-2 (S)** **Related reports:** 343494-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Sep-2008	18-Sep-2008	15	05-Jun-2009	08-Jun-2009	--	WAES0905USA02610	08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2570AA		Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Generalised non-convulsive epilepsy, Headache, Speech disorder, Staring, Tremor, Unresponsive to stimuli

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Act. A 14 year old female with a history of premature birth (36 weeks) on 03-SEP-2008 was vaccinated into the left arm with GARDASIL (lot # 659184/0843X). Concomitant therapy included MENACTRA. Approximately two weeks after the patient got the 1st GARDASIL she started having seizures. The patient had no family history of seizures (also reported as has family history of seizures in paternal aunt) and had always been a healthy person. She was now on medication to help control the seizures (KEPPRA) 500 mg in the morning and 1000 mg at night. On 08-APR-2009 neuroconsults received which was dated from 30-DEC-2008 and 20-JAN-2009. The patient was for evaluation of seizures following multiple episodes of shaking of left arm, staring and unresponsiveness. Episodes first began in late summer 2008 which consisted of just arm shaking lasting less than a minute. In November 2008 the patient complained of headache and the parents noticed the patient with left arm a shaking, dropped the object which the patient was holding, staring and unresponsive. The patient had awareness of event but was unable to speak. And it was resolved after approximately 1 minute. In early December 2008 the patient was found apparently sleeping on bathroom floor and slept two hours after event. The patient was sent for EEG (electroencephalography) which was abnormal and c/w non-convulsive primary generalized epilepsy. Brain MRI (magnetic resonance imaging) was within normal limits. Head CT (computed axial tomography) was within normal limits. Follow up on 20-JAN-2009 with continued episodes. In addition, the patient again found on bath room floor apparently sleeping. So the patient started on KEPPRA although unclear if episodes were seizures. Generalised non-convulsive epilepsy, staring, headache, speech disorder, tremor and unresponsive to stimuli was considered to be immediately life-threatening and other important medical events. A standard lot

Other Meds:

Lab Data: electroencephalography, abnormal X2; magnetic resonance, within normal limits; head computed axial, within normal limits

History: Premature birth

Prex Illness:

Prex Vax Illns:

Vaers Id: **343764-2 (S)** **Related reports:** 343764-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Dec-2008	28-Feb-2009	71	08-Jun-2009	09-Jun-2009	--	WAES0905USA02608	09-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB258AA	1	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	C3032AA	5	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Biopsy bone marrow, Biopsy liver abnormal, Diarrhoea, Fatigue, Gallbladder disorder, Hepatic failure, Hepatitis acute, Hepatomegaly, Jaundice, Pharyngitis, Rash erythematous, Rash papular, Rash pruritic, Splenomegaly, Transaminases increased, Vomiting

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 12 year old female on 19-DEC-2008 was vaccinated intramuscularly into right arm with a first dose of GARDASIL (lot # 661531/1311X). Concomitant therapy included ADACEL and HAVRIX. At time and the months up to March the patient was no local or systemic reaction to any of the Immunizations. On 03-March-2009 the patient came to the office with s/sx of fatigue, abdominal pain and jaundice. UA was done and showed 3 plus Bilirubin and 2 plus urobilirubin. She had hepatomegaly and splenomegaly and pharyngitis. Labs revealed Epstein Barr Positive IgG antibody which may indicate a past infection-mono. The patient returned to the clinic with severe jaundice. The patient had negative Hepatitis panel with abnormal Hepatic levels. The patient consulted Pediatric Infectious Disease Specialist, and repeat labs showed increases in liver enzymes and bilirubin level and US showed enlarged grossly thickened gallbladder wall, mild hepatomegaly and mod splenomegaly. There was no evidence of bilary duct obstruction or pancreatic abnormality noted. Hospital was consulted and patient was admitted where her hepatic levels continued to rise as well as her INR. She was at hospital for almost three weeks and a bone marrow was done. She was discharged 05-APR-2009 and her hepatic functions and INR are continuing to be monitored. This form is filled out at the request of physicians in the event the vaccines contributed to the illness. Doctor called this "seronegative hepatitis". On 16-APR-2009, records was received-for DOS from 17-MAR-2009 to 05-APR-2009: DC DX: DC DX: Liver failure, rash. The patient's Transaminases elevated. Needle biopsy showed acute hepatitis without necrosis. Hepatitis differential diagnosis is infectious versus autoimmune. Skin biopsy showed slig. The patient was presented with sudden onset of emesis, abdominal pain, diarrhea and jaundice 3 weeks prior to admission. The patient developed

Other Meds:

Lab Data: ultrasound, enlarged grossly thickened gallbladder wall, mild hepatomegaly and mod splenomegaly; biopsy, needle biopsy showed acute hepatitis without necrosis; urinalysis, 3 plus Bilirubin and 2 plus Urobilirubin; serum Epstein-Barr VCA, po

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344295-2** **Related reports:** 344295-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Apr-2009	Unknown		15-Jun-2009	14-Jul-2009	--	WAES0905USA02915	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female patient who on 16-APR-2009 was vaccinated with the first dose of GARDASIL. There was no concomitant vaccines administered when the patient received GARDASIL. The patient fainted immediately after receiving the vaccination. The patient lost consciousness for a couple of seconds and then regained consciousness. The patient was evaluated within the office in the Extended Care area. The patient was fine and had recovered. The patient was not hospitalized. The R.N. did not feel that the incident was life-threatening or disabling. The R.N. did not think the patient would continue the GARDASIL series. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344440-2 (S)** **Related reports:** 344440-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Aug-2007	Unknown		02-Jun-2009	03-Jun-2009	--	WAES0905USA02596	03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0780U	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0012U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Adhesiolysis, Anaemia, Cholecystectomy, Colectomy total, Colitis ulcerative, Cough, Crohns disease, Diarrhoea, Explorative laparotomy, Gastroenteritis, Gastrointestinal haemorrhage, Haematochezia, Ileostomy, Inflammatory bowel disease, Intestinal anastomosis, Intestinal obstruction, Laparotomy, Oropharyngeal pain, Pancreatitis, Rectal haemorrhage, Surgery, Transfusion, Urinary tract infection

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 12 year old female with environmental allergies as well as an allergy to penicillin and a history of tonsillectomy was vaccinated intramuscularly with the first dose of GARDASIL (lot# 655503/0012U) on 23-AUG-2007. She was vaccinated with the second dose of VARIVAX (Oka/Merck) (lot# 657752/0780U) on the same date. After receiving vaccine, the patient started having bouts of rectal bleeding and diarrhea. In additional to this she had a very loud barking "chronic" cough. She was finally diagnosed with ulcerative colitis. She had to have a total colectomy resulting with an ostomy and several blood transfusions. On 28-APR-2009 extensive medical record was received for multiple hospital admissions and emergency room visits from MAY 2008-APRIL 2009 with the following discharge diagnoses. Date of service: 03-OCT-2008 to 05-OCT-2008 for inflammatory bowel disease and anemia status post PRBC transfusions. Date of service: 08-OCT-2008 to 31-OCT-2008 for ulcerative colitis, pancreatitis status post laparotomy colectomy with ileostomy, explorative laparotomy with adhesiolysis and wash out. Date of service: 5-JAN-2009 to 08-JAN-2009 ulcerative colitis status post colectomy, acute pancreatitis, pancreas divisum and urinary tract infection. Date of service: 16-FEB-2009 to 22-FEB-2009 for laparotomy cholecystectomy, laparotomy assisted J-pouch ileorectal anastomosis, anorectal pull through, loop ileostomy. Date of service: 03-APR-2009 to 06-APR-2009 for ulcerative colitis, pancreatitis, bowel Obstruction. Multiple emergency room visits with diagnose: on 25-APR-2008 the patient was diagnosed with cough and hematochezia. On 04-MAY-2008 the patient was diagnosed with gastrointestinal bleed and abdominal cramping. On 22-MAY-2008 the patient was diagnosed with Crohn's exacerbation and on 08-JUN-2008 rectal bleeding. On 26-JUL-2008, 27-JUL-2008, and 08-SEP-2008 the patient was diagnosed with Crohn's Fla

Other Meds: Unknown

Lab Data: KUB X-ray, within normal limit; computed axial, (+) for bowel obstruction; ultrasound, GB (+) for thickening; hemoglobin, 9.7; WBC count, 19.8; serum LDH, 540, high; serum lipase test, 1279-, high; serum pancreatic, increased; erythrocyte,

History: Tonsillectomy

Prex Illness: Environmental allergy; Penicillin allergy

Prex Vax Illns:

Vaers Id: **344486-2** **Related reports:** 344486-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Apr-2009	17-Apr-2009	0	17-Jul-2009	19-Aug-2009	RI	WAES0905USA02749	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2877AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial bones fracture, Fall, Loss of consciousness, Syncope

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. It has been received from a physician concerning a 13 year old female with none preexisting illness who on 17-APR-2009 was vaccinated intramuscularly into the left arm with the second 0.5ml dose of GARDASIL (lot # 661846/1312X). Concomitant therapy included the first dose of MENACTRA (Lot # U2877AA), given intramuscularly into the right arm, Post vaccines administration the patient experienced a syncope, fell and fractured nose during syncope event (hit office counter during fall). On an unspecified date a X-ray of nasal bones was performed (results not provided). The listing indicates that one or more of the events required ER visit. At the time of the report, the patient had recovered. The VAERS ID # 344486. In follow-up received 22-JUN-2009, a physician reported that "a few months ago", when a 15 year old female was given 0.5 ml dose of GARDASIL, the child passed out and fell face first resulting in a broken nose. The patient was brought to an unspecified hospital but was not admitted. An x-ray was performed (results not reported). On an unspecified date, the patient recovered. The doctor reported this to VAERS back when it happened. The doctor does not wish to be contacted about this adverse experience. This is a consolidation of two reports concerning the same patient. No further information is available.

Other Meds:

Lab Data: X-ray

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344503-2 (S)** **Related reports:** 344503-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Jan-2008	Unknown		25-Nov-2009	01-Dec-2009	CA		02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	14464	2	Left arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Condition aggravated, Joint swelling, Knee operation, Rheumatoid arthritis

Symptom Text: joint pain in all extremities, fingers, wrists, shoulders, toes, ankles, knees. pain began after second shot, worsened and spread after third and final shot. had knee surgery to remove scar tissue (of unknown origin) in left knee on 12/16/2008. Pain and swelling of joints continued and worsened over time. Patient diagnosed with rheumatoid arthritis on 07/14/2009. Is now being treated for RA with medication and observation. Pain persists and worsens everyday and has become a daily struggle.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **345872-2** **Related reports:** 345872-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-Apr-2009	28-Apr-2009	0	15-Jun-2009	14-Jul-2009	--	WAES0905USA01060	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Back pain, Blister, Gait disturbance, Genital rash, Pyrexia

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female with allergy to (BENADRYL) who on 28-APR-2009 was vaccinated with the first dose of GARDASIL (lot # 660389/1968U) (route not reported). There was no concomitant medication. " 3 hours after getting vaccine" the patient experienced fever, low back pain, hip pain difficulty walking. The patient also mentioned that she had blisters on her labia (she stated she had not had them before). The patient stated she called the pharmacy hot line and was told that this was normal reaction and told to take (TYLENOL) (manufacturer unspecified) after that patient stated she started feeling better. Follow-up information received from registered nurse revealed that the patient had no pertinent medical history. No other vaccines were administered at the same date as GARDASIL. The condition was not considered disabling or life threatening. The patient recovered on an unspecified date. It was unknown if a second dose of GARDASIL will be given. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **345916-2** **Related reports:** 345916-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	29-Apr-2009	29-Apr-2009	0	17-Jul-2009	19-Aug-2009	OH	WAES0906USA02943	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injected limb mobility decreased, Musculoskeletal pain

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female with drug reaction/allergy to SUPRAX who on 24-FEB-2009 as vaccinated with the first dose of GARDASIL (lot # 661703/0651X), intramuscularly. On 29-APR-2009, the patient received the second dose of GARDASIL (lot # 661703/0651X). Concomitant therapy included RECOMBIVAX. On 29-APR-2009 the patient developed a shoulder pain and their arm went numb after receiving her second dose of GARDASIL. The pain disappeared for 2 days and it came back again. The patient had trouble lifting her arm. At the time of reporting, the patient had not recovered. The patient contacted nurse by phone. Additional information has been requested.

Other Meds:

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **346229-2 (S)** **Related reports:** 346229-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Aug-2007	19-Sep-2007	34	30-Jun-2009	01-Jul-2009	--	WAES0906USA02199	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0930U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anorexia, Back pain, Brain lobectomy, Cellulitis, Cerebral atrophy, Choreoathetosis, Convulsion, Coordination abnormal, Dehydration, Developmental delay, Dysarthria, Embolism, Encephalitis, Encephalitis viral, Fatigue, Febrile infection, Gaze palsy, Head injury, Hypercoagulation, Infection, Inflammation, Lethargy, Lymphadenopathy, Motor dysfunction, Muscle twitching, Musculoskeletal stiffness, Neck pain, Oropharyngeal pain, Photophobia, Pyrexia, Respiratory failure, Skin graft, Speech disorder developmental, Surgery, Tachycardia, Venous thrombosis, Viral pharyngitis

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 08-JUN-2007, a 12 year old female with a history of idiopathic thrombocytopenia purpura (ITP) was vaccinated with the first dose of GARDASIL (route and vaccination site not reported) and a dose of VARIVAX (Merck) (route and vaccination site not reported). Concomitant therapy included MENACTRA given also on the same date. On 16-AUG-2007, the patient was vaccinated with the second dose of GARDASIL via intramuscular route into her right arm (lot # 658488/0930U). The patient was diagnosed with encephalitis etiology unknown. Five weeks after administration the patient experienced stiffness of neck, neck pain, back pain, lethargy, no appetite fever for 7 days, then began having seizures which lead to respiratory failure. 1 1/2 year later seizures are ongoing and numerous developmental problems due to brain atrophy. On 13-MAY-2009, the patient's records were received which concern her emergency room (ER) visit on 22-SEP-2007. The patient had a past medical history of idiopathic thrombocytopenia purpura (ITP). The patient presented with complaint of one day history of fever, sore throat and right-sided neck pain. She was diagnosed with viral pharyngitis, right cervical adenopathy most likely due to viral etiology. The patient had an office visit on 26-SEP-2007, with complaint of fever and sore throat, stiff back and shoulders for 4 days, tiredness, decreased appetite, no neck pain. The patient underwent a throat culture which result was negative. The patient had an office visit on 08-JUN-2007: the patient had an immunization visit and received GARDASIL, MENACTRA and VARIVAX (Merck). Assessment: viral infection, pharyngitis. On 20-MAY-2009, ICD-9 codes were received: Infection and inflammatory reaction due to other internal prosthetic device/implant/graft; Unspecified delay in development; Surgical operation, anastomosis/bypass/graft, with abnormal reaction/later complication, no surgical

Other Meds:

Lab Data: throat culture, 09/22/07, negative

History: Idiopathic thrombocytopenic purpura

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346290-2** **Related reports:** 346290-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Apr-2009	15-May-2009	22	03-Jun-2009	04-Jun-2009	VA		04-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	U2668AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	0570X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Patient saw OB-GYN after receiving vaccine and was diagnosed with HPV.

Other Meds: LEKAPRO; Birth Control (by Gyn)

Lab Data:

History: NKDA; allergy to poison Ivy; smokes

Prex Illness: Bladder Infection; UTI

Prex Vax Illns: HPV~HPV (no brand name)~1~17~Patient

Vaers Id: **346308-2 (S)** **Related reports:** 346308-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	29-Aug-2007	Unknown		08-Jun-2009	09-Jun-2009	--	200902272	09-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2381B		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0927U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Arthralgia, Back pain, Gait disturbance, Inflammation, Juvenile arthritis, Laboratory test, Musculoskeletal pain, Pain in jaw, Pelvic pain

Symptom Text: Initial report received on 26 May 2009 from another manufacturer, report # WAES0905USA01139. The initial reporter to the manufacturer had been a health care professional. Verbatim from the report: "Information has been received from a nurse practitioner concerning her 18 year old daughter who on 29-AUG-2007 was vaccinated with her first dose of GARDASIL. Concomitant therapy included MENACTRA. On approximately 05-SEP-2007 the patient experienced lower back, butt, pelvis, and hip pain. The patient was hospitalized from 28-DEC-2008 to 31-DEC-2008 because she could not walk. She had since been diagnosed with juvenile rheumatoid arthritis. The reporter considered the events to be disabling. Follow up information was received from this nurse practitioner. She reported that her daughter on 29-AUG-2007 was vaccinated with GARDASIL (Lot # 658222/0927U). Secondary suspect therapy included MENACTRA (U2381BA). Within a week of the two vaccinations the patient complained of pain in the jaw, lower back, pelvis, hips and buttocks. The symptoms became more severe in about 3.5 months. By December of 2007, the patient had two episodes of difficulty walking and needed help to walk. The patient had an MRI which revealed inflammation with no confirmed diagnosis. The patient was hospitalized in December 2007. In January of 2008 the patient was seen by an Orthopedic Specialist. The patient received joint injections and had a bone marrow biopsy. The patient was also seen by an Oral surgeon and received jaw injections, IM and methotrexate injections, SC. In March of 2008, the patient was seen by a Pediatric Rheumatologist. The nurse stated that she thought that the Rheumatologist reported the case about her daughter to the CDC. The patient was started on HUMIRA injections, IM and methotrexate injections, SC. In June of 2008, the patient was started on REMICADE by infusion every 4 weeks. Laboratory evaluation were performed every 4 weeks. The patient did not have another episode where she could not walk but the patient was never pain free

Other Meds:

Lab Data: MRI: December 2007: revealed inflammation with no confirmed diagnosis.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **346438-2** **Related reports:** 346438-1; 346438-3; 346438-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-May-2009	12-May-2009	0	21-May-2009	22-May-2009	CA	200902144	24-Jul-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2870A		Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAB3334LA		Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1130X		Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0228Y		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: This serious case was received on 13 May 2009 from a health care professional. A 13 year old patient received MENACTRA (lot number U2870AA) intramuscularly in the right deltoid, HAVRIX (manufacturer GSK, lot number AHAB3334LA) intramuscularly in the left deltoid, GARDASIL (manufacturer Merck, lot number 1130X) intramuscularly in the left deltoid, and VARIVAX (manufacturer Merck, lot number 0228Y) intramuscularly in the right arm on 12 May 2009. On 12 May 2009 post vaccination, the patient fainted in the lobby while leaving the Doctor's office. The patient was unconscious for approximately 2-3 minutes. The patient was observed for an hour in the office. The patient sat in a chair and after 10 minutes the patient " pinked up ". The patient recovered and left the doctor's office in stable condition. List of Documents held by sender: None.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **346438-3** **Related reports:** 346438-1; 346438-2; 346438-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-May-2009	12-May-2009	0	15-Jun-2009	14-Jul-2009	CA	WAES0905USA01622	14-Jul-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0228Y		Right arm	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	1130X	0	Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Pallor, Syncope

Symptom Text: Information has been received from an office manager concerning a 13 year old female with no pertinent medical history or drug reactions or allergies who on 12-MAY-2009 was vaccinated with the first 0.5 ml dose of GARDASIL (lot # 661953/1130X) in the left arm. Concomitant suspect therapy included a dose of VARIVAX (lot # 659455/0228Y) administered in the right arm. Other concomitant therapy included (MENACTRA) and (HAVRIX). On 12-MAY-2009, "after receiving all of these vaccinations", the patient became pale and fainted. The patient was still at the physician's office when the symptoms occurred and began to recover within ten minutes. At the time of this report, the patient's final outcome was not specified. No lab tests were done. The patient was seen at the office and sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **346438-4** **Related reports:** 346438-1; 346438-2; 346438-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-May-2009	12-May-2009	0	15-Jun-2009	14-Jul-2009	NV	WAES0906USA00070	14-Jul-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0228Y	1	Unknown	Unknown	
MNQ	SANOFI PASTEUR	M2870AA	0	Unknown	Unknown	
HPV4	MERCK & CO. INC.	1130X	0	Unknown	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAV33341A	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Pallor, Syncope, Tremor

Symptom Text: This report was received from GlaxoSmithKline and was assigned manufacturer report number A0784405A for (HAVRIX). On 12-MAy-2009, a 13 year old female was vaccinated with the first dose of GARDASIL (lot # 661953/1130X). Concomitant suspect vaccination included the second dose of VARIVAX (lot # 659455/0228Y0 given on the same day. Other concomitant vaccinations included the first dose of (HAVRIX) (lot # AHAV33341A) given at 15:30 in the left arm and the first dose of (MENACTRA) (lot # M2870AA) given on the same day. On 12-MAY-2009 at 16:22, 52 minutes after vaccination, the patient experienced fainting, became pale, shaky and fell. The patient required emergency room and/or doctor visit. She had to suit for 10 minutes with her head between her legs and was given an energy bar and an unspecified drink. At the time of the report, the patient recovered from the events. This was originally reported by a healthcare professional. Additional information has been requested.

Other Meds:

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **346454-2** **Related reports:** 346454-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	13-Jul-2007	13-Jul-2007	0	15-Jun-2009	14-Jul-2009	KS	WAES0905USA01417	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia of pregnancy, Drug exposure during pregnancy, Inappropriate schedule of drug administration, Uterine atony

Symptom Text: Information has been received from a registered nurse and a staff member in a office, for the pregnancy registry for GARDASIL, concerning a 24 year old female with renal disease - glomerulonephritis, post partum anemia and history of 5 previous pregnancies, 4 live births, 1 spontaneous abortion who on 20-Sep-2006 was vaccinated with the first dose of GARDASIL (lot# 653735/0688F). On 05-Apr-2007 the patient delivered a normal, healthy male baby (WAES# 0707USA01442). On 20-Nov-2006, the patient was vaccinated with dose of FLUVIREIN (lot# 7135). On 13-Jul-2007 the patient was vaccinated with the second dose of GARDASIL (lot# 657868/0523U). The patient was pregnant, patient's date of last menstrual period was 04-Feb-2008, estimated delivery date 10-Nov-2008. Medication used during pregnancy included prenatal vitamin, iron. On 13-May-2008 24 hour urine cr / cl (creatinine clearance) was performed due to history of renal disease with result WNL. On 05-Sep-2008 ultrasound was performed due to history of renal disease with result within normal limit (WNL). On 11-Sep-2008 non stress test (NST) was performed with result reactive/reassessing. Patient declined MSAFP testing. On 04-Nov-2008, the patient was admitted to the hospital for a repeat C-section and delivered a normal, healthy female baby weighing 7 pounds 11 ounces at 39 week and 1 day pregnancy. The agars score test was preformed with result 9/9. The patient was diagnosed with uterine atony after the delivery of the baby on 04-Nov-2008 and was treated with METHERGINE injection. The patient was also diagnosed with post partum anemia from which she recovered (not considered to be life threatening; no date provided, she had this with a previous pregnancy as well) the patient was discharged from the hospital on 07-Nov-2008 and therefore did not require prolonged hospitalization for any reason. On 20-Nov-2008 the patient was vaccinated with the third dose of GARDASIL (lot# 661531/1311X) No further information is available.

Other Meds: Iron (unspecified) ; Vitamins (unspecified)

Lab Data: Ultrasound, 09/05/08 - WNL; Fetal non stress test , 09/11/08 - reactive/ reassessing ; Apgar score, 11/04/08 , 9/9 ; Urine creatinine, 05/13/08 - WNL.

History: Anemia; Postpartum

Prex Illness: Pregnancy NOS (Lmp = 2/4/2008); Glomerulonephritis

Prex Vax Illns: Vaccine exposure during~HPV (Gardasil)~1~22~Patient

Vaers Id: 346466-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-May-2009	13-May-2009	0	18-May-2009	26-May-2009	IA	IA090005	05-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B036BA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB247AA	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2616AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling, Hypoacusis, Lip swelling

Symptom Text: Pt. at clinic received HPV, MENACTRA, Hep A, Tdap - observed pt. 15 min. after vaccinations. Pt. later reported she couldn't quite hear several hours later at softball practice noted lips swollen (unsure if biting on lip or not). The next morning pt. woke with puffy eyes. Mother reported no respiratory difficulty. Gave BENADRYL with relief.

Other Meds:

Lab Data: None

History: Similar experience with TYLENOL

Prex Illness: No

Prex Vax Illns:

Vaers Id: **346476-1** **Related reports:** 346476-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-May-2009	14-May-2009	0	18-May-2009	20-May-2009	NY		20-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2875AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy, Malaise

Symptom Text: Patient tolerated vaccine well, but upon leaving office (within 5 minutes) was "not feeling well" per mom. While in car, continued to complain of not feeling well and then had a seizure(convulsions of arms, legs, eyes rolled back). The episode lasted approximately one minute. Patient still seemed a little "out of it" for a few hours but by 9 pm, was back to normal. Vaccine was given around 5 pm. Mother had called emergency line, but did not require evaluation in emergency room or office.

Other Meds: none

Lab Data: none

History: History of syncope. evaluated by cardiology and neurology. Two episodes were following blood draws

Prex Illness: no, well check up

Prex Vax Illns:

Vaers Id: **346476-2** **Related reports:** 346476-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-May-2009	14-May-2009	0	05-Aug-2009	06-Aug-2009	NY	WAES0907USA05628	06-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2875AA		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 11 year old (also reported as 15 year old) female with allergy to penicillin (PCN) and POLYTRIM eye drops and a medical history of syncope (cleared by neurologist and cardiologist) who on 14-MAY-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL (lot# 660616/0570X). Concomitant therapy included MENACTRA (lot# U2875AA). The physician reported that the patient received the first dose of GARDASIL "2 months ago" (on 14-MAY-2009). The office was busy and was unable to observe the patient after vaccination (was not observed for 15 minutes post vaccination). When the patient went to the car, she had a 30-second seizure in the parking lot. No treatment was required. The patient recovered. The patient's mother sought medical attention through a telephone call. Upon internal review, seizure was determined to be an other important medical event. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Syncope

Prex Illness: Penicillin allergy; Hypersensitivity

Prex Vax Illns:

Vaers Id: **346485-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	10-May-2007	11-Jun-2007	32	18-May-2009	26-May-2009	NC		26-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Back pain, Dizziness, Dyspnoea, Epistaxis, Fatigue, Feeling abnormal, Gastric ulcer, Hypoaesthesia, Irritability, Memory impairment, Migraine, Mood swings, Myalgia, Pancreatitis, Paraesthesia, Photophobia, Rash, Tremor

Symptom Text: extreme fatigue, migraines, nose bleeds, muscle & joint pain, sensitivity to light, mood swings, irritable, brain fog, dizzy spells, trembles, numbness, back pain, pins & needles, memory fog, skin rashes, pancreatitis, stomach ulcers, shortness of breath

Other Meds:

Lab Data: EEG's, CT scan, Utrasounds, GI problems,

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **346500-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Jun-2008	12-Jun-2008	1	18-May-2009	26-May-2009	WI		29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	4757U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Catatonia, Communication disorder, Convulsion, Dissociation, Dyspnoea, Fatigue, Headache, Hyperventilation, Palpitations, Respiratory arrest, Social avoidant behaviour, Unresponsive to stimuli, Vaccine positive rechallenge

Symptom Text: Shortly after her first shot patient started having episods of what we thought were panic attacks. She had a hard time breathing, her heart would race and she could not catch her breath. After the second shot this so called panic attacks seemed to get worse and she was having them more freqently. She was tired all the time and a bit withdrawn. She had her third shot on June 9th of 2008 and on June 12th I saw one of these episods for the first time. I was stunned. This was no panic attack. She knows it going to happen she get a real intense pain on the top right side of her head. Usually within 30 to 60 seconds of the pain she becomes completly catatonic like. She is unable to comunicate at all. Then she goes into seizure like activity. But, during these seizures she goes into a breathing pattern, she will seizure like activity for about 45 seconds and then she will stop breathing for anywhere from 30 to 40 seconds and this will continue for anywhere from 2 mins to 50 mins. This has been going on for almost a year. She will have these episodes anywhere from 2 to 4 a week. 6/25/09 Hospital records and DC summary received DOS 6/4/09 to 6/9/09. Assessment: Paroxysmal disturbance, etiology indeterminate. Patient presents with stereotypical episodes consisting of sharp stabbing incapacitating discomfort in right parietal or temporal area. Hyperventilation, irregular breathing, unresponsive, dissociated, amnestic. Gardasil Dose #1 (0211U) LA 8/13/07 Gardasil Dose #2 (1266O) RA 1/21/08

Other Meds:

Lab Data: 6/25/09 Hospital records and DC summary received DOS 6/4/09 to 6/9/09. LABS and DIAGNOSTICS: Total Protein 8.4 (H) Globulin 4.1 (H). Video EEG Monitoring - Normal. Pulmonary function test - Mildly increased residual volume otherwise WNL.

History: none. 6/25/09 Hospital records and DC summary received DOS 6/4/09 to 6/9/09. Migraine

Prex Illness: none

Prex Vax Illns: seizures~HPV (Gardasil)~~15~Patient

Vaers Id: 346501-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Mar-2009	02-Apr-2009	17	18-May-2009	26-May-2009	NY		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Cough, Dehydration, Dizziness, Facial pain, Fatigue, Gastritis, Lethargy, Malaise, Nasal oedema, Nausea, Oropharyngeal pain, Pharyngeal erythema, Pruritus, Pyrexia, Respiratory tract congestion, Rhinitis allergic, Rhinorrhoea, Tonsillitis, Upper respiratory tract infection, Vomiting

Symptom Text: She has had dizziness, nausea and vomiting on and off since HPV was given 3/16/09, associated with body malaise. There was no reported fever. she had visited the ER 2x and had received IV hydration in 1 occasion. 7/3/09 ER records received DOS 5/15/09. Assessment: Gastritis - acute, no bleeding. Patient presents with vomiting, abdominal pain, dizziness, tired, lethargic, dizziness, facial pain. Dehydration. Posterior pharynx injected. Returned 5/28/08 with c/o sore throat, cough and fever. DX: Tonsillitis. T=102'F. Throat injected with exudate with swelling of R tonsil. D/C on amoxicillin. 7/8/09 PCP recs received. Pt in for OV 3/16/08 with cough, congestion, fever and sore throat. Dx with viral throat infection. HPV#1 given. On 4/6/08 parent reported that pt had experienced dizziness, nausea and vomiting since receiving the HPV vax. Been 2 ER twice. In for OV with c/o congestion, scratchy throat. itchy nose x 2 days. nasal turbinates and mucosa boggy with mucoid nasal drip. DX: Allergic rhinitis. Acute URI.

Other Meds:

Lab Data: 7/3/09 ER records received DOS 5/15/09. LABS and DIAGNOSTICS: All labs normal. Throat cx (-)

History: 7/3/09 ER records received DOS 5/15/09. Seasonal Allergies.

Prex Illness: She had a sore throat no fever. rapid strep assay was negative and so was the throat culture. Pt in for OV 3/16/08 with cough,

Prex Vax Illns:

Vaers Id: **346563-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	25-Jun-2008	25-Jun-2008	0	19-May-2009	20-May-2009	FR	WAES0807AUS00043	20-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician via CSL as part of a business agreement (manufacturer control # GARD 2008 07 02 001) concerning a 20 year old female with a history of 1 pregnancy and 1 live birth who on 03-JAN-2008 was vaccinated with the first dose of GARDASIL. On 25-JUN-2008 the patient was vaccinated with the second dose of GARDASIL (considered inappropriate schedule of vaccine administration). On 30-JUN-2008 the patient found out that she was 4.5 weeks pregnant. No adverse event was reported. Follow-up information has been received from a completed First Encounter Questionnaire. The date of the patient's last menstrual period was 26-JUN-2008. The patient's pregnancy was confirmed by a urine test. The estimated delivery date is 04-MAR-2009. No further vaccination was administered following the second dose of GARDASIL. Follow-up information has been received from a completed Use in Pregnancy - Pregnancy Outcome Questionnaire. It was reported that the patient did not had any diagnostic tests and the patient had not taken any prescription drugs during her pregnancy. It was also reported that the patient did not have any infections/illnesses during her pregnancy. The patient did not have any complications during pregnancy, labor or delivery. On 28-FEB-2009, the patient had a liveborn female baby weighing 3.1kg who was found to have bilateral talipes positional. The infant did not have any complications other than congenital anomalies. The reporter did not specify whether the infant's bilateral talipes positional was related to therapy with GARDASIL or not. Additional information is not expected.

Other Meds: Unknown

Lab Data: urine beta-human chorionic gonadotropin, ??08, pregnancy confirmed

History:

Prex Illness: Pregnancy NOS (LMP = 26Jun08)

Prex Vax Illns:

Vaers Id: **346564-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	30-Apr-2008	19-Jun-2008	50	19-May-2009	20-May-2009	--	WAES0808USA00976	20-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0243U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner (N.P.), for the Pregnancy Registry for GARDASIL, concerning a 23 year old female with no pertinent medical history, drug reactions or allergies who on 30-APR-2008 was vaccinated intramuscularly with a first 0.5 ml dose of GARDASIL (Lot #656372/0243U). There was no concomitant medication. Subsequently the patient was discovered that she was pregnant. On 05-AUG-2008 a urine pregnancy test was performed at the office and result was positive. Her LMP was 19-JUN-2008. Expected date of delivery was 26-MAR-2009. No adverse effects were reported. The patient had office visit. Follow-up information was received from the N.P. indicating that the patient terminated her pregnancy. The date of the termination was not available. No further information was provided. Upon internal review, pregnancy termination was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: urine beta-human, 08/05/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/19/2008)

Prex Vax Illns:

Vaers Id: **346565-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Oct-2008	07-Oct-2008	0	19-May-2009	20-May-2009	FR	WAES0905USA01341	20-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1358F	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Suffocation feeling

Symptom Text: Information has been received from a Health Authority (case # 98376, local case # IT192/09) concerning a 12 year old female with no previous history reported who on 07-OCT-2008 was vaccinated intramuscularly with a first dose of GARDASIL (lot # 1358F, batch # NG05620). On the same day, 4 hours post-vaccination, the patient experienced dyspnea and suffocation feeling. She was treated with cortisone per os. The outcome was recovered. Dyspnea and suffocation feeling was reported as an other important medical event. Other business partner numbers included E2009-03988. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **346566-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Apr-2008	01-Jun-2008	61	19-May-2009	20-May-2009	FR	WAES0905USA01509	20-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Familial risk factor, Limb reduction defect

Symptom Text: Information has been received from a general practitioner concerning an 18 year old female patient who on 01-APR-2008 was vaccinated with GARDASIL (lot # not reported). Two months after vaccination, the patient developed a deficiency of the lower limbs. Neurological work-up did not show anything in particular. It is noteworthy that the patient's cousin has developed multiple sclerosis. At the time of reporting, the outcome was not provided. Transverse deficiency of lower limb was considered to be an other important medical event by the general practitioner. Additional information has been requested. Other business partner numbers include E2009-03926.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **346568-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Mar-2009	24-Mar-2009	0	19-May-2009	20-May-2009	FR	WAES0905USA01785	20-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1648U	1	Unknown	Intramuscular	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB144AD		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Conversion disorder, Crying, Dizziness, Headache, Syncope

Symptom Text: Information has been received from a health authority concerning a 12 year old female adolescent who on 24-MAR-2009 was vaccinated with a second dose of GARDASIL (lot # 1648U; batch # NH55600, site of administration not reported) and one dose of TWINRIX 720/20 (batch # AHABB144AD, site of administration not reported). Both vaccines were administered by intramuscular route. Before leaving the physician office after vaccination the patient experienced orthostatic syncope lasting for approximately 15 seconds (also reported as 5 seconds). She recovered quickly when legs were put in an elevated position. The patient left the doctor's office 15 minutes after vaccination. 10 minutes later she revisited the doctor's office, complaining about headaches, dizziness, hysterical excitement and crying abnormal. The circulation was always stable. The patient was hospitalized. Subsequently the symptoms disappeared completely and the girl was discharged from hospital. Duration of hysterical excitement, crying abnormal and dizziness reported as 2 hours. On 31-MAR-2009 her doctor reported ongoing headache (outcome not reported). The patient was otherwise healthy and does not take any medication, drugs or alcohol. All vaccinations were well tolerated to date. Causality as per HA of GARDASIL was possible to all events, of TWINRIX was possible to all events except hysterical excitement that was assess as probable. Other business partner's numbers includes: E2009- 03918. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **346592-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Apr-2009	15-Apr-2009	1	19-May-2009	26-May-2009	TX		26-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Headache

Symptom Text: HPV #3 GIVEN 4-14-09 AND PATIENT REPORTS ONSET OF SEVERE HEADACHE ON 4-15-09.

Other Meds: MIDRIN

Lab Data: MIGRAIN

History: MIGRAINS

Prex Illness: DENIED COMPLAINTS OF ILLNESS

Prex Vax Illns:

Vaers Id: **346603-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-May-2009	18-May-2009	0	19-May-2009	26-May-2009	OK		26-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0339Y	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0653X	1	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Nodule, Pyrexia, Swelling

Symptom Text: Patient had baseball size knot with redness, swelling and fever noted. Pt taking benadryl.

Other Meds:

Lab Data:

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: 346608-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Apr-2008	18-Apr-2008	0	19-May-2009	26-May-2009	CA		13-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0388U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ataxia, Condition aggravated, Dizziness, Ear, nose and throat examination normal, Headache, Nausea, Neurological examination normal

Symptom Text: 3 days after second gardasil, pt went to ER for dizziness, ataxia and severe headache. Skull x ray, ct head and lab work all negative. 7/2/09 Received ER medical records of 4/22/2008. FINAL DX: Records reveal patient experienced dizziness, ataxia, nausea, HA x 1 day. Tx w/antivert & d/c to home w/PCP f/u. 5/21/09 Received PCP office record of 4/23/08 s/p ER visit day before for HA & dizziness. ENT & Neuro exams WNL. Dx w/HA.

Other Meds: none

Lab Data: ct head, skull xray, cbc, chem 12, ua, urine tox all negative Medical records received LABS: CBC, CMP WNL. Drug screen (+) for ethanol 2.3 & phenobarbital 1.0

History: none Medical records received PMH: frequent HA, thigh abscess w/hospitalization.

Prex Illness: none, healthy check at that time with normal vision, hearing and urine screen

Prex Vax Illns:

Vaers Id: **346629-2** **Related reports:** 346629-1; 346629-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-May-2009	06-May-2009	1	23-May-2009	28-May-2009	NC		05-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	TD	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Chest pain, Chills, Cough, Gait disturbance, Hyperaesthesia, Myalgia, Nausea, Pain in extremity, Pyrexia, Tremor, Urine colour abnormal

Symptom Text: The day after the HPV vaccination patient started to complain of pain in both arms at appprox 5:30 PM on May 6, 2009. Within 20 minutes she had pain in both arms and both legs. Within another 10 minutes she had pain in her arms, legs, chest, and abdomen. Her hands curled into claws due to the severe amount of pain. We rushed her to the hosital were she was taken in immediately and started on IV pain medication. She had also developed a fever and nausea. Blood and urine tests were clean. She stayed on IV pain medication for another 2 hours or so and then was released with a bottle of vicodin to take every four hours. She had diminishing pain for the next four days. Her family physician said that this "might" be a reaction to the HPV injection and recommended that no further injections of Gardisil be administered. Exactly two weeks later patient had a relapse with associated arm and leg pain, fever and nausea. A return trip to the family Doctor left us with no further explanation than prescriptions for 800 mg Ibuprofin, muscle relaxers, antiinflamitories, and nausea medication and the suggestion that we see a neurologist. Is there an antidote to Gardisil? 6/4/09 ER records received DOS 5/6/09. FINAL DIAGNOSIS: Myalgia. Post vaccination presented with chest and full body pain. Pain occures when touched. Shaking, chills, cough. Painful to walk. States she has dark colored urine.

Other Meds: 6/4/09 ER records received DOS 5/6/09. Dilaudid, Zofran, Vicodan. Flovert, albuterol, guaifenesin.

Lab Data: 6/4/09 ER records received DOS 5/6/09. Blood, Urine. LABS and DIAGNOSTICS: CBC - Neutrophils 73.2% (H) Lymphocytes 17.3% (L). Urinalysis WNL.

History: Mild Asthma. 6/4/09 ER records received DOS 5/6/09. Allergies to: Bees, pineapple, cephalosporins. Asthma, seizure, tonsillectomy.

Prex Illness: Bronchitis

Prex Vax Illns:

Vaers Id: **346629-3** **Related reports:** 346629-1; 346629-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-May-2009	06-May-2009	1	15-Jun-2009	14-Jul-2009	NC	WAES0905USA03238	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2875AA		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Chest pain, Chills, Chromaturia, Cough, Feeling hot, Full blood count, Laboratory test normal, Metabolic function test, Nausea, Pain, Pain in extremity, Pain of skin, Tremor, Urine analysis

Symptom Text: Information has been received from a consumer concerning his daughter, a 13 year old female who was allergic to pineapple and CEPHALOSPORIN and with a mild asthma, received the first dose of GARDASIL on 05-MAY-2009. Concomitant therapy included FLOVENT. On 06-MAY-2009, the patient experienced severe pain in both arms, legs, chest, and abdomen. Her skin could not be touched because she was in so much pain. She was taken to the Emergency Room where she was given pain medication and tests were done for 5 hours. All tests came back negative. About 3-4 days the pain seemed to have gone away. On 20-MAY-2009, the severe pain came back. The patient would not be receiving her second or third dose of GARDASIL. No lot number was provided. At the time of reporting, the patient's severe pain persisted. Follow- up information has been received from a medical assistant who stated that the lot # of GARDASIL was 661952/1129X. The patient received the following vaccines concomitantly on 05-MAY-2009: MENACTRA, (lot # U2875AA) and BOOSTRIX, (Lot # AC52B030AA). On 06-MAY-2009 the patient went to a hospital and complained of shaking, chills, cough and dark colored urine. The patient was treated with IV fluids, DILAUDID and ZOFRAN. The patient had a urine analysis test and a CBC blood test (results not reported). The patient was not admitted to the hospital. On 07-MAY-2009 the physician evaluated the patient. The patient did not received any treatment at the time. On 22-MAY-2009, the patient was seen by the physician's assistant. The patient stated that she was improving but had body aches, nausea, and had a warm feeling with no associated fever. The patient had a CBC, Complete Metabolic Panel (CMP) and CK blood tests. The patient's CK was slightly lower than normal (other results not reported). The patient was not treated at the time. The patient was referred to a neurologist. Additional information has been requested. The patient was seen at hospital.

Other Meds: FLOVENT

Lab Data: Serum creatine kinase 05/??/09 - slightly lower than normal

History:

Prex Illness: Food allergy; Drug hypersensitivity; Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346632-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	27-Feb-2009	27-Feb-2009	0	19-May-2009	26-May-2009	ND		26-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	2	Right leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Chills, Dizziness, Ear pain, Eye pain, Injection site haematoma, Injection site pain, Oropharyngeal pain, Pallor, Pyrexia

Symptom Text: - Pain & bruised at injection site - high fever - Paleness, Weak, dizzy - Sore throat, ear ache, sore eyes - chills 3 days MOTRIN & TYLENOT given

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **346643-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-May-2009	18-May-2009	0	19-May-2009	26-May-2009	CA		26-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	AHAVB329CA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Sensation of heaviness, Syncope, Tremor

Symptom Text: Patient received Hep A on right arm and HPV on Left arm a few seconds later while nurse in room had dazed look and feeling a heavy feeling lay back some shaking + fainted nurse put her feet up she woke up and said she had a weird feeling + no treatment walked out of clinic given water felt better.

Other Meds: None

Lab Data: None

History: None

Prex Illness: Cough; Nasal congestion

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-May-2009	19-May-2009	0	19-May-2009	26-May-2009	CA		26-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2927AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3070AA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Dyskinesia, Hypotonia, Unresponsive to stimuli

Symptom Text: Pt received Tdap, HPV and Menactra and then slumped over into mother's arms motionless, then jerked involuntarily and was layed down with eyes open & unresponsive. About 10 sec. later pt. jerked again and sat up crying and wanting to know what was happening. Pt was kept approx. 20 min. VS stable and accucheck done- 131. Was allowed to leave after taking po fluids.

Other Meds:

Lab Data: Accucheck - 131

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **346674-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		20-May-2009	21-May-2009	--	WAES0905USA01825	21-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a Registered Nurse (R.N) who heard that a 12 year old female patient, who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that the patient died on an unspecified date after receiving the vaccine. It was noted that the death occurred over one year ago. Attempts are being made to verify the existence of an identifiable patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346691-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Apr-2009	22-Apr-2009	0	20-May-2009	21-May-2009	FR	WAES0905USA01980	21-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Nausea, Vomiting

Symptom Text: Information has been received from a Health Authority (HA reference number ES-AGEMED-020958341) concerning a 15 year old female who was administered on the 22-APR-2009 one dose of GARDASIL (lot number not reported) by intramuscularly route (site not reported). It was reported that on the 22-APR-2009, after vaccine administration, the patient presented loss of consciousness for a few seconds, nausea, vomiting and dizziness. The patient fully recovered after three hours. The patient received an ampoule of PRIMPERAN to treat the adverse event. Arterial pressure was 110/60mm Hg, a second reading marked 120/60mm Hg. Cardiac frequency 60ppm, O2 saturation 98%, capillary glucose 75mg/dL. The case reported serious by the Health Authority with other medically important condition as criteria. Other business partner numbers included: E2009-04073. Additional information is not expected. The file is closed.

Other Meds: Unknown

Lab Data: blood pressure measurement, 22Apr09, 110/60 mm Hg; blood pressure measurement, 22Apr09, 120/60 mm Hg, second reading; arterial blood O2 saturation, 22Apr09, 98%; blood glucose, 22Apr09, 75 mg/dL; total heartbeat count, 22Apr09, 60 ppm

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **346693-1** **Related reports:** 346693-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	02-Apr-2008	Unknown		20-May-2009	21-May-2009	FR	WAES0905USA01954	03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Arthritis

Symptom Text: Information has been received from a gynaecologist concerning a 24 year old female who was vaccinated with a first dose of GARDASIL (dose, route and lot number not reported) on 02-APR-2008. The same day, the patient received a booster dose of COVAXIS (SANOFI PASTEUR). Subsequently, in April 2008 (exact latency not reported), the patient developed arthralgia and arthritis in different joints. Nevertheless, the patient received a second dose of GARDASIL (dose, route and lot number not reported) on 19-MAY-2008. Serology for Borrelia and rheumatic disorder was negative (date not reported). Symptoms were ongoing. Upon internal review, arthralgia and arthritis in different joints were determined to be an other important medical events. Other business partner numbers included: E2009-04104. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, Rheumatic disorder serology: negative; diagnostic laboratory test, Borrelia serology: negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **346693-2** **Related reports:** 346693-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	02-Apr-2008	Unknown		21-May-2009	22-May-2009	FR	E200904104	27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Arthritis

Symptom Text: Case received from a healthcare professional on 12-May-2009. It was reported by a gynaecologist that a 24-year-old female patient was vaccinated with a first dose of GARDASIL (lot# not reported) on 02-Apr-2008. The same day, the patient received a booster dose of COVAXIS (lot# not reported). Subsequently, in April 2008 (exact latency not reported), the patient developed arthralgia and arthritis in different joints. Nevertheless, the patient received a 2nd dose of GARDASIL, lot# not reported, on 19-May-2008. Serology for Borrelia and rheumatic disorder was negative (date not reported). Symptoms are ongoing.

Other Meds:

Lab Data: Borrelia and rheuma serology were negative (date not reported).

History: No information reported.

Prex Illness:

Prex Vax Illns:

Vaers Id: **346694-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Mar-2008	Unknown		20-May-2009	21-May-2009	--	WAES0905USA01925	21-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lupus-like syndrome

Symptom Text: Information has been received from a registered nurse concerning an approximately 14 year old female patient who on 22-AUG-2007, 19-OCT-2007 and 07-MAR-2008 was vaccinated with the series of GARDASIL (lot#: 658556/1060U) of all doses) at another office experienced lupus like symptoms with neurological issues. The patient did see a neurologist. The patient also received MENACTRA and DTAP on 15-AUG-2007 (confirmed different data than initial GARDASIL). Nurse did not wish to be contacted. No further information available at the time of reporting. Upon internal review, lupus like symptoms was determined to be an other important medical event. No further information is available.

Other Meds: diphtheria toxoid (+); MENACTRA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **346695-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Jan-2009	Unknown		20-May-2009	21-May-2009	NY	WAES0905USA01680	22-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who was vaccinated with the first dose of GARDASIL IM, 0.5ML on 31-MAY-2008 (lot#: 659441/1446U), the second dose IM, 0.5ML on 26-JAN-2009. After the second dose, the patient developed seizures twice. Concomitant therapy included meningococcal vaccine (manufacturer unknown) and Hep A vaccine (manufacturer unknown). The patient had sought unspecified medical attention. No further information is available at the time of reporting. Upon internal review, Seizures were determined to be an other important medical event. Additional information has been requested. 7/21/09 Medical records received DOS 5/31/08 to 6/27/09. Assessment: Seizures. Parents of patient report several ER visits for seizures.

Other Meds:

Lab Data: Unknown. 7/21/09 Medical records received DOS 5/31/08 to 6/27/09. LABS and DIAGNOSTICS: CBC - WBC 3.4 x10E3/uL (L) Neutrophils 33% (L) Lymphs 51% (H) Monocytes 15% (H) Neutrophils (ABS) 1.1 x10E3/uL (L). CHEM - Glucose 55 mg/dL (L) Postas

History: None. Strep throat pharyngitis.

Prex Illness:

Prex Vax Illns:

Vaers Id: 346696-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-May-2007	12-Dec-2007	209	20-May-2009	21-May-2009	IL	WAES0812USA03680	21-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal growth retardation, Premature labour, Vaginal laceration

Symptom Text: Information has been received from a physician concerning a 19 year old female with no known medical history, allergies or drug reactions who in March 2007, was vaccinated with the first dose of GARDASIL (lot no. route and site not reported) second dose (lot no. route and site not reported) was given in May 2008. There was no concomitant medication. No adverse effects were reported. Subsequently, she became pregnant. The patient's LMP was in April 2008. On 10-JAN-2008 the patient delivered a baby. No laboratory tests were performed. Follow-up information has been received from a nurse who reported that the patient had received the first and second doses of GARDASIL on 13-MAR-2007 and 17-MAY-2007 at another practice. The nurse confirmed the LMP was in April 2007 and the EDD was 25-JAN-2008. The nurse reported that the patient had come late in her pregnancy at 33 weeks of gestation. The nurse reported that the patient was admitted to the hospital on 12-DEC-2007 for preterm contractions and intrauterine growth restriction (IUGR). The nurse did not know how long hospitalization lasted. The nurse stated that the patient delivered early on 10-JAN-2008. It was a vaginal delivery with repair of a laceration. The patient was discharged from the hospital on 12-JAN-2008 following the birth. The patient did not return for her postpartum visit. The patient was seen in July 2008 for a non-pregnancy issue and her annual exam in December 2008. The nurse reported that the baby "seemed to be doing well", no problems were reported for the baby. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 4/1/2007)

Prex Vax Illns:

Vaers Id: 346697-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-May-2008	03-Jul-2008	45	20-May-2009	21-May-2009	FR	WAES0809USA00534	21-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Encephalomyelitis, Hyporeflexia, Paraesthesia, Paralysis flaccid, Sensorimotor disorder

Symptom Text: Information has been received from health authorities (reference number RN20080332), concerning a 14 year old female patient (weight=55kg, height =160cm), other relevant history not reported who on 19-MAY-2008 was vaccinated intramuscularly with a first dose of GARDASIL 0.5mL (batch number not reported). During the week end of 28-JUN-2008 and 29-JUN-2008, she suffered from paraesthesia of her lower limb. Dorsal pain were persisting. On 03-JUL-2008 she developed a flaccid paralysis of lower limbs with sensori-motor deficit, sphincter troubles and suppression of tendon reflex of lower limbs leading to establish a diagnosis of GUILLIAN BARRE SYNDROME. At the time of reporting the patient had not recovered. Follow up information has been received for the Health Authorities on 14-MAY-2009: The patient's date of birth was added. Further investigation were performed with electromyography. The results called into question the previous diagnosis. The accepted diagnosis was now post-infectious acute encephalomyelitis. The patient's condition was slowly improving as she was hospitalized. At the time of the reporting, the outcome was unknown. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as doubtful (C1 S1 I) according to the method of assessment. Other business partner numbers included: E2008-08280. The case is closed. No further information is available.

Other Meds: Unknown

Lab Data: electromyography, encephalomyelitis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 346723-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-May-2009	07-May-2009	1	20-May-2009	28-May-2009	FL		08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Gait disturbance, Hypoaesthesia, Joint injury, Mobility decreased, Muscle spasms, Myalgia, Pain in extremity, Paraesthesia

Symptom Text: Patient received the HPV vaccine in the late afternoon of Wednesday, May 6, 2009. Early on Thursday morning she woke up with pain in her right leg which had started during bedtime. She went to school, and there patient experienced severe pain in her right leg accompanied with pain and numbness on her left arm. she said she couldn't move her forearm and her ring and pinky fingers fo a period of about 5 minutes. About an hour later, around 9 to 9:30 a.m. patient had such pain in her right leg that she fell down. That pain was accompanied by spams in her lower leg and in her foot and toes. She could not walk without help and she was taken to the school nurse from where they called patient's mother. Mother picked her up in less than 20 minutes and took her to the ER. No tests (blood nor ultrasound) were performed. She was given Motrin for the pain and was dismissed with instructions to see pediatrician if she got worse. From Friday through Sunday patient stayed home resting her leg. She had pain on and off and she had difficulty walking most of the weekend. On Monday, May 11, at school, patient's pain got severe again, Mother picked patient up and took her to the pediatrician. Pediatrician ordered blood to be drawn for tests and said she would refer patient to a specialist. On Tuesday, May 12, patient's pain was so severe that she was taken in a wheelchair from the classroom to the nurse's office. Mother picked her up and had to take her home since specialists were not going to see her until the coming week. On Wednesday, May 13, patient had severe pain in the morning while at school, she fell down, Mother picked her up from nurse's office where they had lent her a pair of cruthches to be able to get to the car. Parents called pediatrician to request testing to rule out DVT and parents requested an order for crutches for patient to be able to move around in school. Thursday, May 14, patient was still in pain, and was taken for an ultrasound. No DVT was found. Friday, May 15, patient was able to stay in school with t

Other Meds: 6/4/09 Hospital records received DOS 5/7/2009 and 5/18/09. Motrin. Tylenol. Several years previously - oxandrolone, Lupron.

Lab Data: Normal Ultrasound of the bilateral lower extremity venous system. Normal comprehensive metabolic panel, normal sed rate, normal cbc, normal rheumatoid factor, normal c-reactive protein, negative anachoice screen. 6/4/09 Hospital records

History: 6/4/09 Hospital records received DOS 5/7/2009 and 5/18/09. Evaluation for short stature. Seizure-like activity when very young.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-May-2009	20-May-2009	0	20-May-2009	27-May-2009	MI		27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1702X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2668AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0306Y	1	Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	UF457DA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypoaesthesia

Symptom Text: C/O OF ARM NUMBNESS AFTER RECEIVING VACCINATIONS, THEN 2.5 MINUTES AFTER C/O BECOMING LIGHTHEADED AND DIZZY

Other Meds: NASAL SPARY AND QV4

Lab Data:

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **346763-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-May-2009	19-May-2009	0	20-May-2009	27-May-2009	MD		09-Jun-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2826CA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0336Y	1	Left arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334CA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0650X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal rigidity, Anxiety, Dizziness, Feeling hot, Injected limb mobility decreased, Muscular weakness, Paraesthesia, Presyncope

Symptom Text: 15-20 minutes after vaccine administered Pt began c/o dizziness and weakness in upper extremities. Pt. then began c/o weakness in lower extremities. Pt examined by Dr. . 911 called and ambulance requested. Pt still c/o of weakness and dizziness. Pt A/O x3 with equal strength bilat. Pt transferred to medical center via ambulance. 6/5/09-records received for DOS 5/19/09 began to cry and felt dizzy and hot unable to lift left hand. Required time to calm her down, neuro exam within normal limits, and moving all extremities well. Family history of WPW syndrome. 5/26/09 ED records received DOS 5/19/09. PRIMARY DIAGNOSIS: Vasovagal reaction to an immunization. Presented with dizziness and weakness 18-20 minutes post vaccination. Anxious, abdominal guarding. Tingling left leg and right arm.

Other Meds:

Lab Data: 5/26/09 ED records received DOS 5/19/09. LABS and DIAGNOSTICS: None

History: WOLFE-PARKINSON-WHITE syndrome6/5/09-records received-Family history of WPW syndrome.

Prex Illness:

Prex Vax Illns:

Vaers Id: **346765-1** **Related reports:** 346765-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-May-2009	19-May-2009	0	20-May-2009	27-May-2009	CT	CT200910	16-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2842AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF452CA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Gaze palsy, Hyperhidrosis, Loss of consciousness, Nausea, Opisthotonus, Pallor, Salivary hypersecretion, Syncope, Visual impairment

Symptom Text: Pt felt faint after receiving ADACEL, MENACTRA and GARDASIL. She then became opisthotonic, began salivating, eyes rolled back. Episode lasted about 15 sec. Pt c/o not being able to see. She recovered completely. Vision normalized. 11/02/02 Medical record received for DOS 06/15/09. Neuro visit. Patient passed out s/p vaccines. Brief dizziness before. Diaphoretic after. Pale. No postictal confusion. Nausea/dizziness x1hr after. One or two arm/leg jerks in phase. No rhythmic jerking. No pain. PE wnl. Neuro exam wnl. EEG abnormal but not relevant. Syncopal episode. 11/4/09 Medical records received for date 6/15/09. Neuro consult. DX: syncope. Presenting SX: episodes of passing out following vax, menactra, hepatitis, gardasil. Pt recalls brief dizziness prior to passing out, after passing out pt. states (+)sweating, (+)pale, (+)nausea and dizziness after episode. Parent witnessed 1 or 2 jerks of arms and legs in phase. Assessment: PE WNL, EEG abnormal, showed some sharp waves in the left temporal region.

Other Meds: None

Lab Data: Pt to have EEG

History:

Prex Illness:

Prex Vax Illns: ~Meningococcal (Menactra)~1~0.00~Sibling|~HPV (no brand name)~1~0.00~Sibling|High fever~Tdap (no brand name)~1~11.00~Sibling

Vaers Id: **346765-2** **Related reports:** 346765-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-May-2009	19-May-2009	0	06-Oct-2009	07-Oct-2009	--	WAES0909USA04826	16-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2842AA		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	UF452CA		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Dyskinesia, Electroencephalogram abnormal, Hyperhidrosis, Nausea, Pallor, Syncope

Symptom Text: Information has been received from a Nurse practitioner concerning a 17 year old female patient with no pertinent medical history and with no known drug reactions/allergy who on 19-MAY-2009 was vaccinated with a first and only dose of GARDASIL (route unspecified and lot number: 661953/1130X). Concomitant vaccinations on 19-MAY-2009 included a dose of (lot number: U2842AA) MENACTRA, a dose of ADACEL (lot number: UF452CA). Other concomitant therapy include loratadine (unspecified date). The nurse practitioner reported that after the patient's vaccination on 19-MAY-2009, she experienced seizure. An electroencephalography (EEG) was reported as abnormal (also reported as negative). The patient was referred to a Neurologist who suggested the event was due to anxiety/nervousness. While in the physician office on 29-SEP-2009, the patient refused subsequent vaccination with GARDASIL, due to the seizure. It was reported the patient did not need treatment and that she recovered by the time she left the office on 19-MAY-2009. Upon internal review, seizure was determined to be an other important medical event. Additional information is not expected. 10/13/09 Vaccine records received.

Other Meds: loratadine

Lab Data: electroencephalography, abnormal-negative results. Labs & Diags: EEG- A few sharp waves L temporal region.

History: Allergies: none.

Prex Illness: Anxiety

Prex Vax Illns:

Vaers Id: **346814-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-May-2009	19-May-2009	0	21-May-2009	27-May-2009	MI		27-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0650X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2842AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1384X	1	Left arm	Subcutaneously	
TDAP	SANOFI PASTEUR	C2773AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Headache

Symptom Text: 5 vaccines were administered to this chld. Immediately after the 5th vaccine, the pt. displayed mild seizure activity lasting about 5 seconds. She awoke immediately. Was alittle dizzy and complained of a headache. She did not sustain any injuries. She layed on an exam table for about 15 minutes and seated for another 10 minutes. The family declined emergency care. Spoke to the childs mother the next day. The child felt well enough to attend school.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 346815-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Feb-2009	26-Feb-2009	0	21-May-2009	27-May-2009	AL	AL0908	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Back pain, Body temperature increased, Injection site reaction, Oropharyngeal pain, Pain

Symptom Text: Received HAV and Depo Provera at doctor visit on a.m. In p.m. state symptoms of back pain, epigastric pain, temp. high 105 degrees ache all over, sore throat. Went to ER. Had test for strep, mono- neg. MD told client she had reaction to HPV.

Other Meds: Depo given 2/26/09, other not known

Lab Data: strep and mono

History: NA

Prex Illness: not known (denies)

Prex Vax Illns: nausea, dizziness~HPV (Gardasil)~1~15.00~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346822-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-May-2009	21-May-2009	0	21-May-2009	27-May-2009	NM		27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0385Y	0	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall, Muscle twitching, Syncope

Symptom Text: Administered vaccines at 11:40; promptly fainted; as she fainted she fell from the chair to the floor; had approx 2-3 second duration seizure with twitching of head; first aid administered; VSS with T 97.4 (O); P 82; BP 110/72; notified primary care provider; In speaking with parent who was with the student at time vaccines administered, she indicated that student has history of fainting spells and had not had breakfast.

Other Meds: None

Lab Data: Primary care provider will follow up with parent regarding status/appt

History: Headaches; seasonal allergies;

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346825-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-May-2009	20-May-2009	0	21-May-2009	27-May-2009	MD		27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	IPV	SANOFI PASTEUR	A0492	2	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0525U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: After receiving vaccinations, patient felt faint lightheaded

Other Meds: No

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: 346829-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	12-Aug-2008	27-Apr-2009	258	21-May-2009	22-May-2009	MO		22-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0335X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Patient came in on 8/12/08 for Gardasil and Varivax. Patient was counseled for pregnancy. Patient called on 5/21/09 and stated that she had been pregnant on 8/12/08 and did not know it. She stated she had not missed her period yet when she came in for the vaccinations so she did not think she was pregnant at the time. She delivered twin boys at on 3/23/09 but her EDC was 4/13/09. Baby A weighed 5 pounds 10 ounces at birth and Baby B weighed 5 pounds 7 ounces. Patient took Baby A to pediatrician on 4/27/09 with what she thought was a respiratory illness. Doctor heard a murmur and upon further evaluation was admitted to hospital and flown to another hospital. Infant was diagnosed with Total Anomalous Pulmonary Venous Return and had surgery on 4/29/09. Infant was discharged from the hospital on 5/4/09. Baby B was found to have an innocent heart murmur. Patient also has a 5 year old son and 2 year old daughter who are healthy.

Other Meds: None

Lab Data:

History: Client states she has an allergy to Ibuprofen but no other medical conditions or birth defects.

Prex Illness: Denies any illness at time of vaccination.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346839-1** **Related reports:** 346839-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-May-2009	Unknown		21-May-2009	27-May-2009	TX		27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash, Injection site urticaria

Symptom Text: Urticaria, rash, hives around injection site not sure when it started per patient

Other Meds: Allegra; Nasonex

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **346839-2** **Related reports:** 346839-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-May-2009	12-May-2009	1	28-May-2009	29-May-2009	TX	WAES0905USA02912	29-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic, Urticaria

Symptom Text: Information has been received from a physician concerning a 16 year old female with seasonal allergy and no know drug allergies who on 11-MAY-2009 was vaccinated intramuscularly in the left arm with first dose of GARDASIL (lot number 662229/1497X). Concomitant therapy included ALLEGRA and NASONEX. Within one or two days after vaccination, on approximately 12-MAY-2009, the patient experienced rash and hives on the left arm that was also pruritic. The physician believed that the patient using BENADRYL was an intervention to prevent serious criteria. As of 20-MAY-2009, the patient was recovering. The patient sought medical attention by making a phone call. The reporting physician considered the pruritic rash and hives to be other important medical events. Additional information has been requested.

Other Meds: ALLEGRA; NASONEX

Lab Data: None

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346844-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-May-2009	18-May-2009	0	21-May-2009	27-May-2009	IN		27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Immediate post-injection reaction, Muscle twitching, Staring, Syncope

Symptom Text: The patient fainted immediately (30 secs) after the vaccine, she twitched for 15-20 secs then staring forwards, and then started crying. PR = 72/min, BP - 90/60 mmHg.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346846-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-May-2009	18-May-2009	0	21-May-2009	27-May-2009	IN		27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mydriasis, Pallor, Paraesthesia, Vision blurred

Symptom Text: The patient turned pale, felt tingling all over, pupil dilated and was blurring over. PR = 80 / mier Bp = 90/60.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346850-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-May-2009	20-May-2009	0	21-May-2009	27-May-2009	VA		27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0074Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Skin laceration, Suture insertion, Syncope, Tooth fracture

Symptom Text: HPV vaccine number 1 given . Syncope 5 minutes after vaccine. Fell to floor hit head laceration required sutures broken incisor # 1 Rt upper.

Other Meds:

Lab Data: glucose finger stick, 80+; None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **346920-2** **Related reports:** 346920-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Apr-2009	21-Apr-2009	0	09-Jul-2009	10-Jul-2009	NY	200901706	10-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2866A	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0650X		Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	C3004	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Expired drug administered, Fall, Hypotonia, Loss of consciousness, No reaction on previous exposure to drug, Syncope, Vision blurred

Symptom Text: Initial report received on 21 April 2009 from a health care professional. An 11-year-old female patient had received a first dose of ADACEL (lot number UF455BA, Lot number C3044), a first dose of MENACTRA (lot number U2866AA) and a dose of GARDASIL (manufacturer Merck, lot number not reported) on 21 April 2009. The routes and sites of administration were not reported for any of the vaccines. After receiving the vaccine (time not reported) the patient "went limp;" and was caught by the physician as she fell to the ground. There was no loss of consciousness, but the patient had blurred vision prior to the collapse. It was not reported whether any diagnostic tests or laboratory data were performed. The recovery status of the patient was not reported. Follow up information received on 15 June 2009 from a health care professional who stated the patient did not have a medical history or prior reactions with past vaccinations. The patient received GARDASIL (manufacturer Merck, lot number 0650X) which was noted to have an expiration date of 18 February 2009. ADACEL, MENACTRA, and GARDASIL were all received intramuscularly. The onset time of the symptoms was 2 minutes post vaccination. The reporter stated that the patient recovered after sitting down. No further information was reported. Follow-up information received on 02 and 07 July 2009 from a health care professional and a physician respectively. From the following information received, the case was determined to meet seriousness criteria and was upgraded to serious. Per the reporters, It was unknown which "deltoid muscle" the vaccines were administered into at the well child visit on 21 April 2009. After receiving the vaccines on 21 April 2009, the patient dropped into the nurse's arms losing consciousness for approximately three seconds. No diagnostic tests or laboratory data were completed or performed as they were not needed. The final diagnosis was determined to be syncope. Documents held by sender: None.

Other Meds:

Lab Data: No diagnostic or laboratory work was needed.

History: Not reported

Prex Illness:

Prex Vax Illns:

Vaers Id: **346956-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	26-Oct-2007	01-Mar-2008	127	22-May-2009	26-May-2009	--	WAES0905USA01493	26-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner and a healthcare worker for GARDASIL, a Pregnancy Registry product, concerning a 23 year old female with no medical history who on 26-OCT-2007 was vaccinated with the first dose of GARDASIL (lot# not reported). There was no concomitant medication. In March 2008, the patient became pregnant. It was reported that the patient did not complete the pregnancy and had TOP (termination of pregnancy) but the reason was unknown. It was unspecified if the patient sought medical attention. Upon internal review, the pregnancy termination was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **346958-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Apr-2009	01-May-2009	28	22-May-2009	26-May-2009	FR	WAES0905USA02120	26-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Juvenile arthritis, Tendonitis

Symptom Text: Information has been received from Health Authority on 13-MAY-2009 (reference no. # PEI2009010031) concerning a 15 year old female with no reported medical history who on 03-APR-2009 was intramuscularly vaccinated with a dose of GARDASIL (manufacturer unknown). Four weeks post vaccination, on approximately 01-MAY-2009, the patient experienced manifestation of juvenile idiopathic arthritis associated with enthesitis. The outcome was not reported. Juvenile idiopathic arthritis and enthesitis were considered to be other important medical events. Other business partner numbers include E2009-04080. File is closed.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **346961-1 (S)** **Related reports:** 346961-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-Jun-2007	22-Jun-2007	7	22-May-2009	26-May-2009	NY	WAES0905USA02258	13-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0469U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Angiogram, Computerised tomogram, Condition aggravated, Conversion disorder, Deafness, Echocardiogram, Electroencephalogram, Epistaxis, Gait disturbance, Lumbar puncture, Migraine, Muscular weakness, Myalgia, Nuclear magnetic resonance imaging, Nuclear magnetic resonance imaging brain, Palpitations, Regressive behaviour, Syncope, Vaginal odour

Symptom Text: Information has been received from a physician concerning a 21 year old female with partial hearing loss due to congenital sensory nerve damage, irritable bowel syndrome and gastrooesophageal reflux disease and a history of gastric ulcer perforation who was vaccinated IM with the first dose of GARDASIL, 0.5ml on 15-JUN-2007. There was no concomitant medication. Starting on 22-JUN-2007 the patient experienced migraine headaches and palpitations. In October 2007 the patient received her second IM dose of GARDASIL 0.5 ml, but has not had her third dose. In January 2008, the patient started having syncopal episodes and pseudoseizures. The patient, who was born with hearing loss due to sensory nerve damage, lost her remaining hearing in March 2008. Since the beginning of 2009, the patient had experienced episodes of behavioral regression as well as muscle pain and weakness. Due to the muscle weakness, the patient had limited ambulation. Since April 2009 the patient had recurrent nosebleeds. The patient has required multiple hospitalizations and office visits. The patient had MRI/MRA of head, CT Scan/CTA of head, EEG, echocardiogram, lumbar puncture and angiogram performed (results not reported). At the time of the report (on 18-MAY-2009) the patient was not recovered. The reporter considered the events to be disabling. Additional information has been requested. 7/9/09 Medical records received DOS 6/5/07 to 10/5/07. Patient complains of vaginal odor.

Other Meds: None

Lab Data: Unknown. 7/9/09 Medical records received DOS 6/5/07 to 10/5/07. LABS and Diagnostics: All pending. PAP, GC, Vaginitis Panel, Thyroid panel, Glucose, endocrine studies.

History: Gastric ulcer perforation

Prex Illness: Nerve damage; Irritable bowel syndrome; Partial hearing loss; Gastrooesophageal reflux disease

Prex Vax Illns:

Vaers Id: **346961-2 (S)** **Related reports:** 346961-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-Oct-2007	17-Oct-2007	2	25-Jun-2009	26-Jun-2009	NY	WAES0906USA03810	26-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0742U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Alopecia, Autism spectrum disorder, Blood testosterone increased, Chest pain, Convulsion, Deafness, Emotional disorder, Epistaxis, Flushing, Foaming at mouth, Gastrooesophageal reflux disease, Hallucination, Irritable bowel syndrome, Malaise, Migraine, Nausea, Oedema peripheral, Pain, Paraesthesia, Regressive behaviour, Syncope, Tonic clonic movements, Tremor, Weight increased, Wheelchair user

Symptom Text: Information has been received from a consumer concerning her 21 year old daughter with "immune deficiency runs in family" who on 15-JUN-2007 and on 15-OCT-2007 was vaccinated with first dose (route not reported, lot number 0469U) and second dose (route not reported, lot number 654539/0742U) respectively of GARDASIL. The patient's mother reported that her daughter has been severely ill since receiving the second dose of the vaccine. It was reported that on 17-OCT-2007, the patient's symptoms started with chest pain, migraines, fainting, facial flushing, seizure and nausea. It was reported that she now has emotional regression and spectrum disorder, swelling of legs and feet, inability to walk, pain all over her body, felt "shocks to her brain", clonic tonic symptoms, hair loss, foaming from mouth, nosebleeds, hallucinations, hearing loss, weight gain, shaking like PARKINSON's disease, acid reflux, irritable bowel and high testosterone levels. She reported that her daughter was gone to the hospital over fifteen times and had been admitted nine times to three different hospitals. The patient has been seen by many doctors including neurologist and neuropsychiatrist. She had also had alternative medicine treatments including detoxification, cranial massage and reflexology. It was reported that she was now using a wheelchair and needed to be carried. Lab tests performed included lumbar puncture, cerebral angiogram, EEG and many others which were all negative. As of 19-JUN-2009, the patient had not recovered from the events. Additional information has been requested.

Other Meds: Unknown

Lab Data: spinal tap, Negative; cerebral angiography, Negative; electroencephalography, Negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **346963-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-May-2009	05-May-2009	0	22-May-2009	26-May-2009	FR	WAES0905USA02370	26-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1201U	0	Gluteous maxima	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Disturbance in attention, Headache, Incorrect route of drug administration, Nausea, Syncope

Symptom Text: Information has been received from Health Authority on 15-MAY-2009 (reference no. # PEI2009010030) regarding a case of misuse (inappropriate site (gluteal)) concerning a 16 year old female with no reported medical history who on 05-MAY-2009 was intramuscularly vaccinated with the first dose of GARDASIL (lot #1201U, batch #NG29050) into the right gluteal. On 06-MAY-2009, during sports lessons at school, the patient developed decreased vigilance with a short syncope, subsequently nausea and headache. The decreased vigilance and the syncope lasted for minutes. The patient was hospitalized on an unspecified date. Cardiac dysrhythmias, ventilation disorder and infections were ruled out. The patient recovered "soon". Other business partner numbers include E2009-04171. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **346964-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		22-May-2009	26-May-2009	--	WAES0905USA01937	26-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 13 year old female with cerebral palsy, hydrocephalus and shunt which has became occluded about a year ago and who was a premature infant (24 weeks, weight 11 pounds) who "a couple of months ago" was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). Two weeks later, the patient had a "syncopal episode and possibly seizure". It was reported the patient improved, she did not have any more episodes since. The neurosurgeon told the patient's parents that he could not rule out GARDASIL as a possible cause of the episode. The patient sought unspecified medical attention. Upon internal review possibly seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Premature baby

Prex Illness: Cerebral palsy; Shunt occlusion; Hydrocephalus

Prex Vax Illns:

Vaers Id: **346965-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-May-2009	26-May-2009	--	WAES0905USA01916	26-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a female concerning her daughter, for a pregnancy registry for GARDASIL, who on an unspecified date was vaccinated with the first dose of GARDASIL. The reporter stated that the patient did not know at the time of the vaccination that she was pregnant. The patient had the baby 3 weeks after the vaccination. It was reported the patient sought unspecified medical attention. It was reported that the baby died. The patient was 9 weeks pregnant. Upon internal review, baby died at 9 weeks was determined to be an other important event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **346967-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		22-May-2009	26-May-2009	--	WAES0905USA01868	26-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, No reaction on previous exposure to drug

Symptom Text: Information has been received from a pharmacist concerning a 19 year old female with no pertinent medical history who was vaccinated with the second dose of GARDASIL (lot#, dose, route and site of administration not reported). There was no concomitant medication. The patient experienced seizures after receiving the second dose, and she went to an emergency room for treatment. The patient recovered from seizure. Seizure was considered to be life threatening by the pharmacist who stated that this case might have been already reported by the patient's physician. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346979-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	24-Mar-2009	24-Mar-2009	0	22-May-2009	26-May-2009	FR	WAES0905USA02472	26-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Fatigue, Headache

Symptom Text: Information has been received via a GARDASIL Access Program concerning a female child (age not reported) who on 24-MAR-2009 was intramuscularly vaccinated with the first 0.5 ml dose of GARDASIL. Later that night she was brought to the hospital complaining of tiredness, headache and had seizures. She was observed and no treatment was given. Observations of the child were continued at home and the child was fine. Upon internal review, seizures was determined to be an other important medical event. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346992-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	22-May-2009	22-May-2009	0	22-May-2009	27-May-2009	GA		27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: As medication was being injected, became faint. Has not done this with other injections. Once patient sat for a few minutse and sipped on Coke, felt much better.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **346997-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	15-Apr-2009	16-Apr-2009	1	22-May-2009	27-May-2009	MD		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	ANTH	EMERGENT BIOSOLUTIONS	FAV164	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2735AA	1	Left arm	Intramuscular	
	TYP	SANOFI PASTEUR	B0347-2	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0572X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Pain in extremity

Symptom Text: Pt c/o pain in left arm after receiving her first dose of anthrax. The pain started one day after receiving the dose and lasted for 3 days.

Other Meds:

Lab Data:

History: Latex Allergy

Prex Illness: Good health

Prex Vax Illns:

Vaers Id: **346998-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-May-2009	19-May-2009	0	22-May-2009	27-May-2009	TX		27-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0653X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2872AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	M0055Y	2	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anorexia, Chills, Headache, Hypoaesthesia, Injected limb mobility decreased, Injection site anaesthesia, Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth, Nausea, Photophobia, Pyrexia

Symptom Text: CLIENT RECEIVED VACCINE ON 5/18/2009 ON THE LEFT ARM ONE INCH BELOW THE TDAP. SHE EXPERIENCED FEVER OF 102, CHILLS, SENSITIVITY TO LIGT, HEADACHES, LOSS OF APPETITE, NAUSEA,NUMBNESS TO SITE AND LOSS OF FEELING IN ARM. TODAY THE SITE IS 3"X 3.5" RED,WARM, SLIGHTLY SWOLLEN AND VERY PAINFUL TO SLIGHT TOUCH. PULSE OF 88, TEMPERATURE OF 97 DEGREES. FINGERS TO LEFT HAND ARE PINK, WARM, CAPILLARY REFILL <3 SECONDS. ABLE TO MOVE FINGERS FREELY. ABLE TO LIFT LEFT ARM BUT C/O PAIN WHEN ARM IS LIFTED ABOVE SHOULDER LEVEL. REVIEWED THE SIDE EFFECTS LISTED IN THE PRODUCT FOLDER WITH CLIENT. INFORMED CLIENT NOT TO SCRATCH SITE AS SITE CAN BECOME INFECTED. INFORMED CLIENT IF SITE BECOMES MORE PAINFUL AND OOZES PUS AND HAS ODOR AND INCREASES IN SIZE AND HAS A THROBBING SENSATION TO SEE PHYSICIAN. REVIEWED THE SIGNS AND SYMPTOMS OF INFECTION WITH CLIENT. INFORMED CLIENT IF FINGERS BECOME COOL AND FEEL NUMB TO SEE PHYSICIAN. ADMITS TO HAVING HEADACHE BECAUSE WISDOM TEETH ARE COMING OUT. INFORMED CLIENT TO CHECK ARM WITH BROTHER IN LAW WHO IS A NURSE IF HAVING MORE PROBLEMS OR SEE HER PHYSICIAN.

Other Meds:

Lab Data:

History:

Prex Illness: WISDOM TEETH COMING OUT

Prex Vax Illns:

Vaers Id: **346999-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-May-2009	22-May-2009	0	22-May-2009	27-May-2009	NJ		08-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1318X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1496X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bradycardia, Dizziness, Heart rate decreased, Hyperhidrosis, Hypotension, Immediate post-injection reaction, Orthostatic hypotension, Pallor, Presyncope, Syncope

Symptom Text: Immediately after administering the vaccine, the patient experienced near-syncope: pallor, diaphoresis, hypotension and bradycardia. This lasted over 1.5 hours until she was transported by EMS to the ED. Her BP baseline was 125/75 with pulse 108, but during the event BP was 80's/50's with pulse in the 50's. Standing caused dropping of BP and pulse and diaphoresis and near-syncope. 7/7/09 ER records received DOS 5/22/09. Assessment: Vasovagal Syncope. Patient instantly developed lightheadedness and had syncopal episode. Presented with low blood pressure and pulse.

Other Meds: Vyvanse - not taken on day of vaccine

Lab Data:

History: allergy to fruit; attention-deficit disorder; Kawasaki disease as a child that led to coronary aneurysm that completely resolved per cardiologist. 7/7/09 ER records received DOS 5/22/09. ADD, T&A.

Prex Illness: no acute illness. 7/7/09 ER records received DOS 5/22/09. LABS and DIAGNOSTICS: None.

Prex Vax Illns:

Vaers Id: **347002-1** **Related reports:** 347002-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-May-2009	21-May-2009	1	22-May-2009	27-May-2009	IN		27-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2819AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Left arm	Intramuscular	
HEP	MERCK & CO. INC.	1040X	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0558X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Retching

Symptom Text: Patient complained of dizziness, nausea and dry heaves. The symptoms lasted approximately 8 hours. No treatment

Other Meds:

Lab Data: None

History: Hypoglycemic Allergic to sulfa

Prex Illness: No

Prex Vax Illns:

Vaers Id: **347002-2** **Related reports:** 347002-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-May-2009	21-May-2009	1	17-Jul-2009	19-Aug-2009	--	WAES0906USA02396	20-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2819AA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	0558X	0	Right arm	Intramuscular	
HEP	MERCK & CO. INC.	1040X	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Retching

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act., concerning an 18 year old female patient with hypoglycaemia and sulfonamide allergy who on 20-MAY-2009 was vaccinated with the first dose of GARDASIL (lot n. 658271/0558X), intramuscularly in the right arm. Secondary suspect therapy included the first dose of RECOMBIVAX HB (lot n. 662421/1040X), intramuscularly in the left arm. Concomitant therapy included BOOSTRIX (lot n. AC52B030AA) and MENACTRA (lot. U2819AA0029). On 21-MAY-2009, the patient complained of dizziness, nausea and dry heaves. The symptoms lasted approximately 8 hours. The patient did not receive any treatment. The original reporting source was not provided. The VAERS ID # 347002. No further information is available.

Other Meds:

Lab Data: None

History: Hypoglycaemia

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **347030-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-May-2009	Unknown		22-May-2009	27-May-2009	IL		27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0222Y	1	Right arm	Subcutaneously	
	MMR	MERCK & CO. INC.	1727X	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2906AA		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Rash maculo-papular

Symptom Text: (R) Posterior arm - 1 area maculopapular 5 cm diam. erythema (MENACTRA) (B) Posterior arm - 1 area maculopapular 15 cm diam. (VARICELLA)

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **347058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	14-May-2009	15-May-2009	1	22-May-2009	27-May-2009	AR		27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0339Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0651X	1	Left leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Redness and swelling to left arm approximately 12-15 hours after injection, warm compress, Allgrax X 48

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 347170-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Mar-2009	01-Apr-2009	31	26-May-2009	27-May-2009	FR	WAES0905POL00002	27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Ileitis

Symptom Text: Information has been received from a patient's mother concerning a 16 year old female who in approximately March 2009, was vaccinated with the first dose of GARDASIL. In the beginning of April 2009 the patient was admitted to the hospital. Ileitis was diagnosed. The patient was treated with antibiotic (unspecified). After week the patient was discharged from the hospital with recommendation of continuing therapy with antibiotic. The patient's mother was not sure if ileitis was related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **347171-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	01-Dec-2008		26-May-2009	27-May-2009	FR	WAES0905USA02375	27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdomen scan normal, Abdominal pain, Oral contraception, Pelvic pain, Personality change

Symptom Text: Information has been received from a gynecologist concerning a 15 year old female patient with no relevant medical history who had received the three doses of GARDASIL (lot# not reported) in 2008. In December 2008, the patient experienced abdominal pain episode and acute enteric intussusception was suspected which was not found after an abdominal pelvic scan. Any anomaly was found. Pelvic pains occurred for which, no etiology was found. Oral contraceptive was given. In April 2009, the patient went to physician's office for character disorder. At the time of the report the outcome was not reported. The adverse experiences were determined to be other important medical events. Other business partner numbers include: E2009-04157. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **347173-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Apr-2009	03-Apr-2009	0	26-May-2009	27-May-2009	FR	WAES0905USA02587	01-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myoclonus, Syncope

Symptom Text: Initial information received by Health Authority (reference number ES-AGEMED-419167244) regarding a 14 year old female who was administered on 03-APR-2009 a dose of a GARDASIL (lot# not reported) 0.5mL by intramuscular route (site of administration not reported). It was reported that after vaccine administration, on the 03-APR-2009, the patient presented a syncope with myoclonic jerks. The patient recovered spontaneously on the same date. Case reported as serious by the HA with other medically important condition as criteria. Other business partner number included: E2009-04217. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 347183-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Apr-2009	22-Apr-2009	0	26-May-2009	27-May-2009	FR	WAES0905USA02589	27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1882U	2	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthropathy, Electromyogram normal, Injection site oedema, Injection site reaction, Mononeuritis, Paraesthesia

Symptom Text: Information has been received from a health agency (case n. 98687) (Local case n. IT205/09) concerning a 12 year old female patient who on 22-APR-2009 was vaccinated with the third dose of GARDASIL IM In the right deltoid (batch#: NJ21670; lot#: 1882U). No other vaccines administered during the 4 weeks prior to vaccination. On the same day 22-APR-2009 the patient presented with an adverse reaction for which she was evaluated at the vaccination clinic and admitted to the hospital on the following day (23-APR-2009). She was discharged on 26-APR-2009 with the diagnosis of circumscribed edema and mononeuritis of the upper right limb. She was treated with prednisone and paracetamol. On 06-MAY-2009 an electromyography was performed in day hospital and resulted within limits, however objective exam revealed a persistence of paresthesia and disturbance of the metacarpal and interphalangeal section of the right hand precluding the normal opposition of the thumb and index. At the time of reporting the patient's condition had improved. The final outcome was not reported. Other business partner numbers include E2009-04191. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **347184-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Mar-2009	02-Apr-2009	7	26-May-2009	27-May-2009	FR	WAES0905USA02369	27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1695U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy, No reaction on previous exposure to drug

Symptom Text: Information has been received from Health Authority on 15-MAY-2009 (reference no. # PEI2009009746) concerning a 15 year old female who on 26-MAR-2009 was intramuscularly vaccinated with the second dose of GARDASIL (Lot #1695U, batch #NH25730) into the deltoid muscle. On 02-APR-2009 the patient developed central facial palsy (left side). Lumbar puncture, magnetic resonance imaging (MRI) and laboratory findings showed normal results. The patient had not recovered at the time of reporting. It was also reported the patient was vaccinated with the first dose of GARDASIL (Lot #1427U, batch #NH15200) on 20-JAN-2009 and was well tolerated. Facial palsy was considered to be an other important medical event. Other business partner numbers include E2009-04170. File is closed.

Other Meds: Unknown

Lab Data: Spinal tap, ??09, normal; magnetic resonance imaging, ??09, normal; diagnostic laboratory test, ??09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **347186-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Mar-2009	06-May-2009	57	26-May-2009	27-May-2009	FR	WAES0905USA02151	27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1883U	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Sudden hearing loss, Vertigo, Vomiting

Symptom Text: Information has been received from a health professional concerning a 15 year old female who on 10-MAR-2009 was vaccinated with a first dose of GARDASIL (lot# 1883U, batch # NH50860, intramuscularly in right upper arm). On 06-MAY-2009 the patient experienced vertigo that aggravated within 1.5 hours. The patient vomited after feeling as if sitting on a swing moving backwards and as if the entire room had a heavy list to the right. She also experienced a sudden hearing loss on the right ear. The patient was examined at the Ear, Nose and Throat at the hospital, where it was established that the problem originated from the auditory organ and that there was no brain damage. The patient was hospitalized at the children's clinic for a data tomography (DT, normal) and a lumbar puncture (quick test was normal). The hospital will return the final results of the lumbar puncture. Due to the hospitalization the case was considered serious. The outcome was at the time of reporting not yet recovered. Case is closed. Other business partner numbers included E2009-04117. Additional information has been requested.

Other Meds: Unknown

Lab Data: computed axial tomography, normal; spinal tap, quick test was normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 347187-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Apr-2009	07-Apr-2009	1	26-May-2009	27-May-2009	FR	WAES0905USA01981	27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chills, Headache, Nausea, Pain, Pyrexia

Symptom Text: Initial information received from a foreign Health Authority (Reference number ES-AGEMED-524959332) on 11-MAY-2009 regarding an 18 year old female who was administered on the 06-APR-2009 the second dose of a GARDASIL (Lot not reported), route and site not reported. One day after vaccine administration, on 07-APR-2009, the patient presented a frontal progressive cephalea, fever and nausea. It is also reported that the patient had shivers, events did not stop after taking GELOCATIL. The patient was hospital admitted on an unspecified date, a lumbar puncture was performed. The patient was diagnosed with a febrile clinical picture after vaccination with GARDASIL and with pain after lumbar puncture. Cephalea, fever and nausea are the only adverse events coded in the Health Authorities report. The patient recovered on April 2009, exact date not reported. According to the regional pharmacovigilance center this case was notified by fax on 30-APR-2009 by GSK (possible mistake, they are referring to agency). "Further information is expected when we receive the case through the electronic transmission" is written in the Health Authorities report. This case is probably a duplicate of case WAES: 0904USA03703 (E-2009-03957). Confirmation from the Health Authorities is pending. Other business partner numbers include E2009-4128. Additional information has been requested.

Other Meds: Unknown

Lab Data: spinal tap, ??Apr?09, febrile clinical picture; body temp, ??Apr?09, Fever

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **347189-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Mar-2009	01-Mar-2009	0	26-May-2009	27-May-2009	FR	WAES0903AUS00046	27-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Hypoaesthesia, Syncope, Vomiting

Symptom Text: Information has been received from a pharmacist, via CSL as part of a business agreement (manufacturers control No. CSL 2009 03 10 LS 2) concerning a female student who on approximately 10-FEB-2009, "approximately four weeks ago" was vaccinated with GARDASIL as part of a school vaccination program. Subsequently the patient fainted. At the time of reporting on 10-MAR-2009, the patient had fully recovered. The vaccination program included approximately 100 students and there was one other adverse event reported of a female who was hospitalised (NWAES 0903AUS00045). Follow up information has been received from a pharmacist. The patient was reported as a 12 year old female with no previous allergies who in March 2009, was vaccinated with GARDASIL. Subsequently, in March 2009, the patient fainted, started vomiting, had a numb arm and headache and was hospitalized. Subsequently, 72 hours later, the patient recovered from fainting, vomiting, numb arm and headache. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **347196-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Mar-2009	02-Apr-2009	2	26-May-2009	28-May-2009	NM		28-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Rash generalised

Symptom Text: Adolescent received vaccines on 3/31/09. Mother called on 4-2-09 morning with adolescent having fever, rash all over the body. However no difficulty breathing. Instructed to bring to office same day. However mother decided to keep her home. Obviously she got better within 2-3 days.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **347245-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	16-Mar-2009	17-Mar-2009	1	26-May-2009	28-May-2009	MD		28-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus

Symptom Text: 24 hours after receiving GARDASIL # 1, developed redness and itching both legs (thigh to ankle). Skin became more red with NIVEA. No fever.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **347279-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	30-Mar-2009	04-Apr-2009	5	26-May-2009	28-May-2009	TX		28-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oral papilloma

Symptom Text: Patient developed mucosal wart inside lower lip 5 days after receiving second HPV vaccine.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **347497-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.3	M	11-May-2009	Unknown		27-May-2009	29-May-2009	AR		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Right leg	Unknown	
	PNC7	WYETH PHARMACEUTICALS, INC	018704	1	Left leg	Unknown	
	ROTHB5	MERCK & CO. INC.	0066Y	1	Unknown	By Mouth	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: This patient was accidently given HPV

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **347548-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-Nov-2008	01-Feb-2008	-274	27-May-2009	28-May-2009	TN		06-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Dyskinesia, Infertility, Muscle spasms, Muscle twitching, Panic attack

Symptom Text: I have random twitches and involuntary muscle movement/spasms in my legs, calves, quads, ankles, feet, and toes and sometimes in my fingers and bottom. The date I've listed below was the 3rd Gardasil shot. The first shot was September 2007. Without looking at the doctor records, I don't have the date, but I remember the month and year. Also, the adverse affect was just sometime in between the first and 2nd shot in 2008 7/1/09 Consultant OB-GYN records received DOS 5/28/09 to 6/9/09. Assessment: Twitches. Twitches in legs and fingers. Concerns about infertility. Anxiety, panic attacks.

Other Meds: 7/1/09 Consultant OB-GYN records received DOS 5/28/09 to 6/9/09. Oral contraceptives, multivitamin, prenatal vitamin.

Lab Data: 7/1/09 Consultant OB-GYN records received DOS 5/28/09 to 6/9/09. LABS and DIAGNOSTICS: PAP test (-), Progesterone.

History: 7/1/09 Consultant OB-GYN records received DOS 5/28/09 to 6/9/09. Allergy to codeine.

Prex Illness:

Prex Vax Illns:

Vaers Id: **347553-1** **Related reports:** 347553-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	21-May-2009	24-May-2009	3	27-May-2009	28-May-2009	MA		28-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Chills, Dyspnoea, Pain, Pyrexia

Symptom Text: Three days after experienced fever of 103, chills, body aches, chest pain and shortness of breath.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **347553-2** **Related reports:** 347553-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	21-May-2009	24-May-2009	3	15-Jun-2009	14-Jul-2009	--	WAES0905USA03645	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Diarrhoea, Dyspnoea, Headache, Pyrexia, Viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female with papanicolaou smear abnormal and a colposcopy (21-MAY-2009), who on 21-MAY-2009 was vaccinated with 0.5 ml of the first dose of GARDASIL (Lot. 661953/1130X), no other vaccine was administered at the same time. Concomitant therapy included multiple vitamins (unspecified). On 24-MAY-2009, the patient experienced a headache, slight diarrhea and fever. The patient went to the emergency room (ER), but was not admitted. The patient did not have a urinary tract infection (UTI) or a cervical infection. Her white blood cell count (WBC) was normal. The ER's discharge summary stated, "viral illness". On 26-MAY-2009, the nurse practitioner spoke with the patient who reported an intermittent fever of about 100 degrees, chest pain and some difficulty breathing. The patient was told to contact her primary care physician. At the time of this report, the patient's status was unknown. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: cervical smear, 05/??/09, No cervical infection; WBC count, 05/??/09, normal; urinalysis, no UTI

History: Colposcopy

Prex Illness: Papanicolaou smear abnormal

Prex Vax Illns:

Vaers Id: **347717-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		28-May-2009	29-May-2009	--	WAES0905USA02514	29-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Pain in extremity, Paralysis, Pyrexia

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a female patient who received two doses of GARDASIL. The patient had no difficulties after the first dose. After the second dose the patient experienced a high fever, soreness in her arm and temporary paralysis. The patient sought medical attention through an office visit. Upon internal review, temporary paralysis was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **347718-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Jul-2007	01-Sep-2007	51	28-May-2009	29-May-2009	FR	WAES0905USA02367	29-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Infection susceptibility increased, Tension headache

Symptom Text: Information has been received from a Health authority (reference number PEI2009009794) concerning a 16 year old female who on 12-JUL-2007 was vaccinated with the first dose of GARDASIL (lot number, injection route and site not reported). In autumn 2007, the patient developed chronic tension headaches and increased infection susceptibility. The patient was hospitalized on an unspecified date. Thorough investigation including physical examination, MRI and X-ray showed normal results. Sinusitis, tumor, inflammatory events, migraine, epilepsy and metabolic disorder were ruled out. But a postural deformity was diagnosed (not otherwise specified). As tat the time the complaints were not attributed to the vaccination, the second dose of GARDASIL (lot number 1536F and batch number NG01520) (injection route and site not reported) was administered on 05-NOV-2007. The symptoms were persisting after this second dose. The patient has not recovered at the time of reporting. The case was closed. Other company numbers included: E2009-04168. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, normal; X-ray, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **347719-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Mar-2009	28-Apr-2009	42	28-May-2009	29-May-2009	UT	WAES0905USA02266	29-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Vertigo

Symptom Text: Information has been received from a certified medical assistant concerning a 17 year old female who on 17-MAR-2009 was intramuscular vaccinated with the first 0.5ml GARDASIL vaccine (Lot # 661846/1312X). The patient has no medical history. There was no concomitant medication. Approximately 6 weeks after administration, the patient developed a "seizure-like activity" and "dizziness" when she was getting out of the bathtub. She saw a neurologist and had an MRI which was negative. The patient now has occasional vertigo. The patient was considered to be recovering at the time of the report. The patient has not received any additional doses yet. Follow up information has been received from this certified medical assistant. She reported that no other vaccines were administered at the time of GARDASIL dose. She could not confirm that the patient actually had a seizure (stating that "seizure-like activity" was what was reported by the patient's mother), and could not give a more definitive AE onset date. Upon internal review, "seizure-like activity" was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Magnetic resonance, negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 347720-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	19-Mar-2008	04-May-2009	411	28-May-2009	29-May-2009	MI	WAES0905USA02293	29-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Carcinoma in situ, Cervical dysplasia, Loop electrosurgical excision procedure

Symptom Text: Information has been received from a physician concerning a 22 year old female with no medical history who was vaccinated with her first (lot# 658222/0927U), second (lot# 658222/0927U) and third (lot# 659964/1978U) dose of GARDASIL on 22-AUG-2007, 08-SEP-2007 and 19-MAR-2008, respectively. On 04-MAY-2009 the patient was diagnosed with high grade squamous intraepithelial lesion carcinoma in situ after a PAP test. The patient had a LEEP Procedure done on 15-MAY-2009. The patient sought unspecified medical attention. Additional information received via telephone from a medical assistant on 19-MAY-2009. Medical assistant reported that the patient's second dose of GARDASIL was administered on 08-NOV-2007 (not 08-SEP-2007 as previous reported). There were no concomitant vaccines administered with GARDASIL vaccinations. The medical assistant confirmed that the patient had a PAP smear test on 04-MAY-2009 and had a LEEP on 15-MAY-2009. The reporter did not know the patient's recovery status. The patient did not have a scheduled follow up visit with physician at the time. The reporter considered high grade squamous intraepithelial lesion carcinoma in situ to be an other important event and disabling. Additional information has been requested.

Other Meds: None

Lab Data: cervical smear, 05/04/09, diagnosed with high grade squamous intraepithelial lesion carcinoma in situ

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **347721-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	13-May-2009	13-May-2009	0	28-May-2009	29-May-2009	--	WAES0905USA02211	29-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Pyrexia, Throat tightness

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female who experienced fever a few hours after receiving the first dose of GARDASIL. The patient received the second dose of GARDASIL on 13-MAY-2009 and after a few hours, the patient's mother called in stating that the patient felt like her throat was closing that she couldn't breathe. Lot #'s were not available. Patient was brought to the emergency room but she was not admitted in the hospital. At the time of the report the patient's AE improved. Follow-up information has been received from a nurse practitioner who stated that the patient was treated in the emergency room. The patient was treated with BENADRYL IV and fluids. The patient was not admitted to the hospital. The patient had recovered. Follow-up information received from a medical assistant at the nurse practitioner's office stated that the patient's mother called the office and reported that her daughter felt as if her throat was closing. The physician then advised that the patient be taken to the hospital. Upon internal review, felt like throat was closing and couldn't breath, requiring treatment with IV antihistamine, were considered to be other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 347722-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
35.0	F	12-Jan-2009	04-May-2009	112	28-May-2009	29-May-2009	--	WAES0905USA01582	29-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breast cancer in situ, Breast mass, Breast tenderness, Inappropriate schedule of drug administration

Symptom Text: Information has been received from an investigator concerning a 35 year old female with no known drug allergies, with HIV and alcohol use who entered a study. On 16-JUL-2008 the patient was vaccinated with the first dose of GARDASIL 0.5 mL via injection. On 11-SEP-2008, she was vaccinated with the second dose of GARDASIL 0.5 mL via injection and the third dose of GARDASIL was administered on 12-JAN-2009. Concomitant therapy included Kaletra, Truvada and Loestrin. Approximate duration of use of concomitant medications was reported as 2 months. On 09-APR-2009, the patient presented to the clinic for a non-study visit with complaints of feeling a lump on her right breast for three weeks. Upon evaluation by provider, the subject was referred for a mammogram for diagnosis. The mammogram was performed on 16-APR-2009 and revealed an abnormality in the right breast that was highly suspicious for ductal carcinoma in situ. On 20-APR-2009 the patient was seen for the right breast lump and right breast tenderness. There was no nipple discharge, no axillary nodes of skin changes were noted. There was no family history of breast cancer. A biopsy was recommended by clinic provider. The biopsy was performed on 04-MAY-2009. On 07-MAY-2009 the patient received pathology results from the breast biopsy that confirmed the lump was ductal carcinoma in situ (grade 4). The patient was scheduled to visit with specialist to explore treatment options on 12-MAY-2009. Follow-up information was received in a pathology report. The patient had 1x1 cm palpable mass. On 04-MAY-2009, a right breast core needle biopsy was performed and ductal carcinoma in situ, high grade) was diagnosed. The patient's ductal carcinoma in situ (grade 4) persisted. The reporting investigator classified the event of ductal carcinoma in situ (grade 4) as possibly related to study therapy with GARDASIL. The patient's ductal carcinoma in situ (grade 4) was considered to be an other important medical event. Additional information is expected.

Other Meds: Truvada; Loestrin; Kaletra

Lab Data: Mammography, 04/16/09, abnormality in R breast/highly suspicious for ductal carcinoma in situ; Biopsy, 05/04/09, confirmed lump as ductal carcinoma

History:

Prex Illness: Alcohol use; Acquired immunodeficiency syndrome

Prex Vax Illns:

Vaers Id: 347729-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	11-Feb-2009	11-Feb-2009	0	28-May-2009	29-May-2009	--	WAES0903USA01606	29-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MMR	MERCK & CO. INC.	1366X		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse for GARDASIL and MMR II, Pregnancy Registry products, concerning a female patient with no known drug allergies who on 11-FEB-2009 was vaccinated with the first dose of GARDASIL (lot# 659184/0843X), 0.5 mL, intramuscular administration. Concomitant therapy administered on 11-FEB-2009 included MMR II (lot # 662817/1366X) albumin status rHA, and Tdap (unspecified). It was reported that the patient was pregnant. LMP was in January 2009, EDD was 08-OCT-2009. No adverse effect was reported. The patient sought medical attention at the physician's office. Follow up information was received from a licensed practical nurse. She reported that the patient received the GARDASIL, MMR II and Tdap (manufacturer unknown) early in her pregnancy. The licensed practical nurse stated that this patient had her pregnancy confirmed at the health department (urine hCG test) and after a few weeks, she called to report that she had a miscarriage (specific date not provided). The licensed practical nurse reported she requested that the patient come in for follow up, but she had not seen or heard from her since the phone call. Upon internal review miscarriage was determined to be an other important medical event. No further information is available. Additional information has been requested.

Other Meds:

Lab Data: urine beta-human, 02/??/09, Positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/1/2009)

Prex Vax Illns:

Vaers Id: **347730-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	31-Oct-2008	01-Nov-2008	1	28-May-2009	29-May-2009	FR	WAES0904USA03856	29-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction, Enlarged uvula, Oropharyngeal swelling

Symptom Text: Information was obtained on request by the company from the agency, via a Public Case Details forms, concerning a 24 year old female who on 31-OCT-2008 was vaccinated with GARDASIL IM (therapy dose, site and lot number unknown). Subsequently the patient experienced swollen uvula of which presents like anaphylaxis, 24 hours post injection. On 02-NOV-2008 the patient recovered. The agency considered the event was possibly related to therapy with GARDASIL. The agency considered oropharyngeal swelling to be an other important medical event. The original reporting source was not provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **347734-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	28-May-2009	28-May-2009	0	28-May-2009	29-May-2009	VA		29-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Pt passed out

Other Meds: Birth control

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 347923-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Feb-2009	Unknown		28-May-2009	02-Jun-2009	CA		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Chest pain, Dyspnoea, Hypoaesthesia, Limb discomfort, Nodule on extremity, Paraesthesia, Rash, Rash erythematous, Rash macular, Sensory loss

Symptom Text: Rash, decreased sensation and decreased strength in the left arm. 7/7/09 Hospital records received DOS 5/11/09 to 5/15/09. Assessment: Disturbed sensory perception, mononeuropathy. Patient presented with blotchy streaked erythematous left upper arm rash, raised nodule. Left arm numbness C5-T1 dermatomes. Complaints of tingling and pain. Swelling. No sensation to sharp or dull touch. Episode of chest pain and shortness of breath. 7/20/09 ICD-9 Codes: 354.9, 782.1, 346.90, 781.3, 781.2, 787.91, 723.1, 789.00, 782.0

Other Meds:

Lab Data: MRI C-Spine & MRA Brain/brainstem are normal. 7/7/09 Hospital records received DOS 5/11/09 to 5/15/09. LABS and DIAGNOSTICS: Electromyogram and Nerve Conduction tests pending. Multiple immunological tests pending. CT scan pending. MRI and

History: none. 7/7/09 Hospital records received DOS 5/11/09 to 5/15/09. Bilateral wrist fractures. Abdominal pain and fever. Milk allergy. Fell on head several times. Vertical nystagmus. Neck pain.

Prex Illness: no

Prex Vax Illns:

Vaers Id: **347924-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	22-Jan-2009	05-Feb-2009	14	28-May-2009	29-May-2009	OR		01-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NOT DOCUMENTED	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaccine positive rechallenge

Symptom Text: patient had rash c/ second injection, but thought it was due to starting a new OTC product. 3rd immunization given, and rash reappeared.

Other Meds:

Lab Data:

History: hyperlipidemia, generalized anxiety d/o

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **347953-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Jan-2009	14-Jan-2009	0	28-May-2009	29-May-2009	FL		29-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Hypoaesthesia, Insomnia, Paraesthesia, Pyrexia

Symptom Text: Patient complained of "high" fever several hours after injection (although did not have a thermometer). Sweating, could not sleep, numbness and tingling in both legs. Symptoms resolved in approximately 24 hours. Was patient's 2nd injection.

Other Meds: Low-ogestrel

Lab Data:

History: none

Prex Illness: Possible URI

Prex Vax Illns:

Vaers Id: **348102-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Mar-2009	11-Mar-2009	0	29-May-2009	01-Jun-2009	FR	WAES0903USA05356	01-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	508BB	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0779X	0	Left arm	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	XA0013A	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Erythema, Localised oedema, Musculoskeletal pain, Oedema peripheral, Peripheral coldness, Rash, Skin discolouration

Symptom Text: Case received from a nurse on 12-MAR-2009. A 14 year old female patient with no relevant medical history received the first dose of GARDASIL (batch number: NJ328320, lot #: 0779X) via intramuscular route in her left deltoid on 11-MAR-2009, and the first dose of MENINGITEC (batch #: not reported) via intramuscular route in her right deltoid on 11-MAR-2009 and the first dose of ENGERIX-B (batch number not reported) via intramuscular route in her right deltoid. 3 minutes later the patient experienced bilateral oedema and redness on her hands, with shoulder pain and rash on her left wrist. She had recovered on the same day from shoulder pain and rash on her wrist but on 13-MAR-2009 from bilateral oedema and redness. Steroid treatment with prednisolone was given on the same day of the vaccination without success. The patient recovered spontaneously. The reporter was not sure of which vaccine might have originated the reaction. She had no concomitant treatment. Re-challenge information expected in May 2009. Additional information received through PV form received on 16-MAR-2009: The nurse was also contacted by phone on the same day to confirm all the data. Initials of the patient were modified. Suspect vaccine previously reported as MENINGITEC was in fact MENJUGATE (batch number XA0013A) and the batch number of ENGERIX-B was SO8BB. The prednisolone was SOLU-DACORTINA 50 mg. Posture of patient was changed to drain the oedema. The patient recovered on the following day (previously reported on 13-MAR-2009). The form completed by the nurse did not mention the adverse effect reported in the initial version (shoulder pain and rash on the left wrist previously reported), however this information was confirmed through the phone call made on the same day the form was received. Case originated from medical information query (09/031). Follow-up information was received from the health authorities on 18-MAR-2009: The batch number for ENGERIX-B was SO8BB was modified into 508BB. Following GARDASIL, MENJUGATE and ENGERIX-B, the pati

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 348105-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	06-Apr-2009	30-Apr-2009	24	29-May-2009	01-Jun-2009	--	WAES0905USA03370	03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chiropractic, Fatigue, Headache, Lymphadenopathy, Musculoskeletal stiffness, Nausea, Neck pain, Vaginal discharge, Vaginal infection, Vomiting, Vulvovaginal dryness

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female with unspecified drug reactions/allergies and medical history who on 13-FEB-2009 was vaccinated IM with 0.5ml first dose of GARDASIL (lot number:661531/1311X) and second dose on 6-APR-2009 (Lot number 661952/1129X). Concomitant therapy included hormonal contraceptives (unspecified) and Adderall. Laboratory test were not performed. The nurse practitioner stated the patient received the second dose of the vaccine and experienced swollen glands on the left side of the neck. On 30-APR-2009, the patient went to see her primary care physician with neck pain and then a chiropractor. Subsequently on 6-MAY-2009, the patient came to see the nurse practitioner and she felt that intervention to prevent serious criteria was referring the patient to an ENT physician (Ears, nose, throat physician) to determine if a biopsy was needed. The outcome of the patient was not recovered and she sought medical attention by nurse and physician's office. Additional Information has been requested. 6/2/09 Medical records received DOS 2/13/09 to 5/27/09. FINAL DIAGNOSIS: Lymphadenopathy. Post vaccination reports feeling tired, sits with head turned to left, neck pain. Took several doses of Advil followed by nausea and vomiting. Headaches. Tenderness left lateral neck, palpable lymph node. Later several swollen glands. Chiropractic adjustments. Vaginal discharge. Vaginitis. Vaginal dryness.

Other Meds: Adderall tablets; Hormonal contraceptives. 6/2/09 Medical records received DOS 2/13/09 to 5/27/09. Imitrex, Advil, Keflex, Ortho Tri-Cyclen, Advair, Adderal

Lab Data: None. 6/2/09 Medical records received DOS 2/13/09 to 5/27/09. LABS and Diagnostics: Pending - CBC, monospot, HIV.

History: None 6/2/09 Medical records received DOS 2/13/09 to 5/27/09. Migraine, bacterial vaginosis, asthma, ADD, appendectomy.

Prex Illness:

Prex Vax Illns:

Vaers Id: **348108-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Apr-2009	21-Apr-2009	0	29-May-2009	01-Jun-2009	FR	WAES0905USA03436	01-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anterograde amnesia, Loss of consciousness, Presyncope, Syncope, Tremor

Symptom Text: Information has been received from a health authority (reference # ES-AGEMED-019209344) concerning a 14 year old female who was administered on 21-APR-2009 the first dose of GARDASIL (batch number not reported) by intramuscular route (site of administration not reported). After administration of the first dose of GARDASIL, on 21-APR-2009, the patient suffered a syncope with a vasovagal reaction which the patient recovered from spontaneously. According to the patient's father, 10 minutes later, the patient presented tremors and loss of consciousness. The patient says that she dreamt of male nurses not remembering where she was or what she was doing in a health center. In the health authorities' report, only anterograde amnesia, tremor and syncope are coded. The patient recovered on that same date. No further information reported. Case reported as serious by the HA with other medically important condition as criteria. Case is closed. Other business partner numbers include E200904319.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **348110-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-May-2009	13-May-2009	0	29-May-2009	01-Jun-2009	FR	WAES0905USA03440	01-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vertigo

Symptom Text: Information has been received from the Health Authority (reference number ES-AGEMED-506465248) concerning a 12 years old female who on 13-MAY-2009 was vaccinated with a dose of GARDASIL (batch number not reported) by intramuscular route (site of administration not reported). On 13-MAY-2009, the patient presented with cephalea and night vertigo after vaccine administered. It was unknown if the patient sought medical attention. The patient recovered from vertigo on 14-MAY-2009, and recovered from cephalea on 16-MAY-2009. Case reported as serious by the HA with other medically important condition as criteria. The case was closed. Other company numbers included: E2009-04316. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **348111-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-May-2009	18-May-2009	0	29-May-2009	01-Jun-2009	FR	WAES0905USA03443	01-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ14700	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Cold sweat, Immediate post-injection reaction, Loss of consciousness, Malaise, Mydriasis, No reaction on previous exposure to drug, Pain, Resuscitation

Symptom Text: Information has been received from a pediatrician concerning a 14 year old female patient who on 18-MAY-2009 was vaccinated with the third dose of GARDASIL (Batch # NJ14700). No reaction reported following the first two doses. Immediately after third dose of vaccination, the patient experienced pain. Ten minutes later, according to the reporter, the patient presented vagal malaise with sensation of weakness, cold sweat, then total loss of consciousness with bilateral mydriasis. There was no dribbling or urinary emission. Considering the seriousness of the reactions, the pediatrician gave a punch in the heart of the patient to resuscitate her. The patient had regained consciousness after a short period of time that the reporter could not quantify. Pain, malaise, weakness, cold sweat, loss of consciousness and mydriasis were considered to be other important medical events by the pediatrician. Other business partner numbers include: E2009-04247. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **348113-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Oct-2008	01-Oct-2008	0	29-May-2009	01-Jun-2009	FR	WAES0905USA03590	01-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Balance disorder, Dysarthria, Eye pain, Fatigue, Grip strength decreased, Paraesthesia, Sensory loss

Symptom Text: Information has been received from a health authority concerning a 15 year old female who was vaccinated with the first dose of GARDASIL (i.m, batch number and site of administration not reported) primo October 2008. In October 2008 (not further specified), the patient experienced sensation loss of hands and feet. It was reported that the patient had problems to hold the cutlery properly. The symptoms lasted for 2-3 weeks. In February 2009, the patient experienced the similar symptoms (not further specified), but this time, sensation loss of feet disseminated proximally to the middle of the thighs during the following 2-3 after start of symptoms. On 08-APR-2009, the patient was seen by a physiotherapist who noticed impaired balance. During the following days, the patient experienced paraesthesia of hands, feet, nose, and of the back of the head. In addition, the patient experienced articulation problems and tiredness. On 23-APR-2009, the patient experienced pain behind left eye. Subsequently, the patient also experienced pain behind right eye. MR scan of the cerebrum on 28-APR-2009 revealed increased signal intensity in the periventricular, corpus callosum and subcorticalis. Several lesions in brainstem. MR scan of spinal column was performed on 28-APR-2009. Increased signal intensity was observed posterior medulla at Th9 and C4. Blood samples (not further specified) revealed no abnormalities. No concomitant medicine or concurrent diseases. The patient was vaccinated with the second and third dose of GARDASIL (i.m., batch number and site of administration not reported) in the second week of December 2008 and ultimo March 2009, respectively. It was reported that the patient was hospitalized (not further specified) and had not recovered. Other business partner's numbers included: E2009-04267. Additional information has been requested.

Other Meds: None

Lab Data: magnetic resonance imaging, 28Apr09, increased signal intensity, several lesions in brainstem; magnetic resonance imaging, 28Apr09, spinal MRI: increased intensity posterior medulla at Th9 and C4

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348150-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	20-May-2009	20-May-2009	0	29-May-2009	02-Jun-2009	CA		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Eye movement disorder, Feeling hot, Paraesthesia

Symptom Text: a few minutes after i got the 1st shot, body felt warm and tingly. then i had a small seizure according to the tech, but did not lose consciousness. the whole incident was less than 10 secs. he said my eye movement rapid. 9 days later, felt the same previous symptoms, but did not have a seizure.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **348166-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-May-2009	28-May-2009	1	30-May-2009	02-Jun-2009	MN		02-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	SANOFI PASTEUR	C3158AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache, Hypersomnia, Hypophagia, Pyrexia

Symptom Text: Fever - 102.7; Headache; Fatigue; Was given tylenol 480 mg every 4-6 hours for 16 hours; slept most of the day; drank liquids but did not eat; no other symptoms; headache only lasted a few hours; fever and fatigue lasted ~16 hours

Other Meds: Multivitamin with Fluoride

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: None~ ()~NULL~~In Patient|None~ ()~NULL~~In Sibling1

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348189-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	19-May-2009	19-May-2009	0	29-May-2009	02-Jun-2009	MI		06-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Loss of consciousness, Tremor

Symptom Text: Patient was given initial dose of Gardasil vaccine in (R) deltoid. Almost immediately after vaccine was given she c/o dizziness & then lost consciousness. Was sitting in a chair and was able to elevate her legs on another chair. Regained consciousness after about 10 secs. Transferred her to a table where she laid with legs elevated 10 min. Provided juice to client. Cont'd to feel shaky after 25 min. Phoned he mom who picked her up & drove her home. B/P 110/70 HR50.

Other Meds: Birth control pills

Lab Data:

History: None Known

Prex Illness: None

Prex Vax Illns: felt faint~Hep B (no brand name)~UN~0.00~Patient

Vaers Id: 348237-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Apr-2009	22-Apr-2009	14	01-Jun-2009	02-Jun-2009	FR	WAES0905USA03442	02-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1316U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Demyelination, Diplopia, Headache, No reaction on previous exposure to drug, Paraesthesia

Symptom Text: Information has been received from a hospital paediatrician concerning a 16 year old female with a medical history of epileptic seizure (once) in the course of idiopathic partial epilepsy and a flu-like infection at the end of January 2009 who was vaccinated with a second dose of GARDASIL (Lot#, injection site and route not reported) on 08-APR-2009. About 2 weeks past of vaccination the patient experienced double version, cephalgia and paraesthesia of the right hand and was hospitalized on 04-MAY-2009. Magnetic resonance imaging showed several demyelinating foci of the brain and of thoracic segment 12 (th12). Tentative diagnosis was acute demyelinating encephalomyelitis. The symptoms resolved spontaneously and the girl recovered completely (duration not reported). The patient was discharged on an unspecified date. Follow-up Magnetic resonance imaging and neurological examination are planned after 3 months. The first dose of GARDASIL (Lot#1316U, Batch#45640) administered on 07-JAN-2009 was well tolerated. Additional information has been requested. Other business partner numbers include E2009-04245.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, MRI showed central demyelinating foci and foci at thoracic segment 12 (th12)

History: Epileptic seizure; Flu-like illness

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348238-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Apr-2009	29-Apr-2009	1	01-Jun-2009	02-Jun-2009	FL		02-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2823AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Myalgia

Symptom Text: Patient complain of muscle pain in left deltoid muscle. Pain persists one month after injection.

Other Meds:

Lab Data:

History:

Prex Illness: NONE- physical exam

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348240-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		01-Jun-2009	02-Jun-2009	NY	WAES0905USA03626	02-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the second dose of GARDASIL. It was reported that "3 weeks after getting the second dose of GARDASIL" the patient experienced a seizure. The outcome of the patient was unknown. Upon internal review seizure was determined to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **348253-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		01-Jun-2009	02-Jun-2009	FR	WAES0905USA03741	02-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune disorder

Symptom Text: Information has been received from a general practitioner concerning a female patient, who (reporter's daughter, age unspecified) experienced either Basedow's disease, Crohn's disease or other autoimmune disease after receiving the first dose of GARDASIL (batch number not reported) on an unspecified date. It is noteworthy that the physician decided to stop the vaccination following to that reaction. Furthermore, the reporter mentioned that the patient had received the first dose more than one year ago. At the time of reporting, the outcome was not provided and the reporter could not be reached. The reporting general practitioner considered Autoimmune disorder to be other important medical event. Other business partner numbers include E2009-04452. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **348260-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-May-2009	20-May-2009	0	01-Jun-2009	02-Jun-2009	FL		04-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2877AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Crying, Fall, Head injury, Nervousness, Pain in extremity

Symptom Text: I assessed a 12 year old female who was alert and oriented but appeared nervous, comfort measures were taken. I proceded to administer the vaccines. I asked the child if she was okay, she replied that she was alright, but her left arm was in pain. The child left the room as I began to provide vaccines for the third child in the family. She was out in the hallway near the exam room. We heard a loud thump,the father abruptly left the room and was beside his child. She was awake and cyring and responded with a nonverbal manner by nodding her head to the questions being asked of her. Dr. came and asses the child. After the assessment, Dr. recommended that the child be taken to the emergency room; for she had sustained a lump on her back of her head. 911 was called. Shortly after the call was placed the paramedic arrived and took the child.

Other Meds:

Lab Data: UNKNOWN

History: NONE KNOWN

Prex Illness: NONE KNOWN

Prex Vax Illns:

Vaers Id: **348262-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Dec-2008	31-Dec-2008	1	01-Jun-2009	02-Jun-2009	CA		02-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Injection site warmth, Lymphadenopathy

Symptom Text: severe swelling in lympyh node on side of chest. Site swollen, warm to the touch. Lasted approx. 5 days. Doctors perplexed at the location of the swollen node(s) since they bypassed others before settling a distance away for the shot site, but on the same side of the body as injection site. Problem appeared within 48 hours

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348281-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-May-2009	29-May-2009	0	01-Jun-2009	02-Jun-2009	TX		22-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	0124Y	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3158AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Immediately following injection patient had syncopal episode for 15 seconds. She had Flailing of arms/ Legs when she was unconscious, as nurse was exposing pt to smelling salt pt upper.

Other Meds:

Lab Data:

History:

Prex Illness: None, Dr Appointment

Prex Vax Illns:

Vaers Id: **348291-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-May-2009	21-May-2009	1	02-Jun-2009	04-Jun-2009	IL		07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Balance disorder, Convulsion, Disorientation, Dizziness, Dysarthria, Fall, Fatigue, Headache, Inappropriate affect, Staring, Unresponsive to stimuli

Symptom Text: Pt had unwitnessed seizure on 5/21/09. H/O probable seizure activity in the past 6 wks. After seizure, pt has had complaint of headache, dizziness, weakness, balance difficulty. 7/6/09 MR received for DOS 5/21-24/2009 with D/C DX: Seizure. Headache. Pt presented to ER after episode of unresponsiveness with limb flexion, staring, and fall. Disoriented with slurred speech, inappropriate affect, weakness, tiredness and severeH/A after. Recent episodes of involuntary fluttering of R hand. Started on Depakote.

Other Meds:

Lab Data: EEG: 5/22/09, irregular diffuse spikes, polyspikes, generalized synchronized spikes suggestive of generalized seizure disorder. labs and Diagnostics: Head CT (-). EKG WNL. EEG abnormal. MRI brain WNL.

History: Near-syncope episodes. PMH: Allergy to Amoxicillin

Prex Illness: No

Prex Vax Illns:

Vaers Id: **348310-1 (S)** **Related reports:** 348310-2; 348310-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-May-2009	21-May-2009	0	02-Jun-2009	03-Jun-2009	TX	WAES0905USA03247	09-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2877AA		Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blood pressure decreased, Contusion, Dizziness, Fall, Head injury, Headache, Loose tooth, Mouth injury, Syncope, Toothache, Vaccination complication

Symptom Text: Information has been received from a physician concerning a 24 year old female patient who on 26-AUG-2008 was vaccinated with the first dose of GARDASIL (Lot#660557/0072X), 0.5ml. On 27-OCT-2008 the patient was vaccinated with the second dose of GARDASIL (Lot#660557/0072X), 0.5ml, and on 21-MAY-2009 the patient was vaccinated with the third dose of GARDASIL (Lot#661953/1130X), 0.5ml. MENACTRA (Lot#U2877AA) was administered during the same visit. There was no other concomitant medication. On 21-MAY-2009, 5 minutes after receiving her third dose of GARDASIL, the patient fainted and fell on the floor. She was now experiencing severe headache and she also had a "busted lip" and her upper tooth was loose. The patient was not recovered now and she had sought medical. Additional information was received from a medical assistant that the patient was admitted to a hospital on 21-May-2009. The admitting diagnoses were reported as syncope, head trauma, severe headache, reaction to vaccine, contusion to mouth, and laceration to lower lip. It was also noted that the patient's two front teeth were loose. When the patient was discharged and the patient's recovery status were both unknown. The patient was not scheduled for a follow-up visit with the physician. Additional information has been requested. 7/8/09 Received PCP & vaccine records. Patient was seated during injection of vaccines and after 5 min, fell onto the floor sustaining facial injuries. Observed in office 40 min. BP prior ro vaccines 110/80; after fall 8/40; then returned to 110/70. Stable & d/c to home w/parents. Phone contact w/parent that evening revealed patient c/o HA, toothache & dizziness. Admitted to hospital for 23 hr observation. Remained stable & d/c to home. Seen again in PCP office for cellulitis/abscess left thigh/hip. No further problems. 6/9/09 Hospital records received DOS 5/21/09. Admitting diagnosis: syncope, head trauma, headache, reaction to immunizations.

Other Meds:

Lab Data: None. 6/9/09 Hospital records received DOS 5/21/09. LABS and DIAGNOSTICS: CHEM - Sodium 143 mml/L (H) Carbon Dioxide 26 mml/L (H). CBC - Hematocrit 30.7% (L) RBC Morph 1+ Aniso. CT Brain - Normal. Pregnancy Test (-).

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **348310-2 (S)** **Related reports:** 348310-1; 348310-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-May-2009	21-May-2009	0	28-Jun-2009	30-Jun-2009	TX		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2877AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Contusion, Dizziness, Face injury, Headache, Syncope

Symptom Text: SYNCOPE,CONTUSION TO FACE,HEADACHE,DIZZINESS

Other Meds: NONE

Lab Data: CT HEAD WO CONTRAST,BASIC METABOLIC PANEL,CBC

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **348310-3** **Related reports:** 348310-1; 348310-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-May-2009	21-May-2009	0	06-Jul-2009	07-Jul-2009	TX	200902740	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2877A	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Computerised tomogram, Fall, Head injury, No reaction on previous exposure to drug, Syncope

Symptom Text: This case was received from a physician on 26 June 2009. A 14-year-old female, with a history of shrimp allergy, received the following vaccinations on 21 May 2009: a first dose of MENACTRA (lot number U2877AA) and a third dose of GARDASIL (Merck, lot number not reported). The patient was in a seated position two minutes post-vaccination, when she experienced a syncopal episode, fell to the floor, and hit her head. She had a possible injury to her tooth, and underwent a CT of the head. The patient had not experienced any adverse reactions following her first two doses of GARDASIL. At the time of the report, outcome was unknown.

Other Meds:

Lab Data:

History: Allergy to shrimp.

Prex Illness:

Prex Vax Illns:

Vaers Id: 348311-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Oct-2008	01-Oct-2008	0	02-Jun-2009	03-Jun-2009	FR	WAES0905USA03755	03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Inflammation, Musculoskeletal pain

Symptom Text: Information has been received from Health Authorities in a foreign country (BX20090316, BX0900344) concerning a 19 year-old female patient who received the first, second and third dose of GARDASIL respectively in July 2008, October 2008 and January 2009. In October 2008, one to two weeks after receiving the second dose, the patient presented with progressive pain in the posterior face of the right knee. The evolution was progressive until January 2009. At that time, the patient had developed pain in both knees, in the lateral face of hips and in the right shoulder. The patient was a HLA-B27 antigen carrier. Biologically, a slight inflammatory syndrome was noticed on 8-APR-2009 with an erythrocyte sedimentation rate (ESR) at 27 and C-reactive protein at 8. It is noteworthy that her father, grand father had a medical history of spondylarthropathy non designated. Knees ultrasonography was normal. Standards X-rays showed moderate troubles of the static lumbopelvic without sacroilitis. Other investigations (cutaneous, abdominal, neurological, cardiopulmonary) were normal. There was no arguments in favor of a spondylarthropathy. Pain persisted but improved with NSAID treatment. At the time of the reporting, the patient had not yet recovered. The Health Authorities assessed the causal relationship between the reported reaction and vaccination as doubtful (C2 S1 I1) according to foreign method of assessment. Other company numbers included: E2009-04462. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound, Knees-Normal; X-ray, Moderate tumbles-see narrative; diagnostic laboratory test, Other investigations-Normal see narrative; serum C-reactive protein, 08Apr09, 8; erythrocyte sedimentation rate, 08Apr09, 27

History: Leukocyte antigen B-27 positive; Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **348312-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-May-2009	16-May-2009	5	02-Jun-2009	03-Jun-2009	FR	WAES0905USA03775	03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ00020	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epistaxis, Fall, Haematoma, Headache, Injection site erythema, Injection site inflammation, Injection site swelling, Loss of consciousness, Pyrexia, Somnolence, Syncope

Symptom Text: Information has been received from a health professional concerning a 16 year old female with a history of WOLFF-PARKINSON-WHITE syndrome who was administered on 11-MAY-2009 the first dose of GARDASIL (batch number NJ00020) by intramuscular route on the deltoid muscle. It was reported that on 16-MAY-2009, the patient suffered a syncope while she was in the bathroom, suffering a nose bleed and a face hematoma. The patient lost consciousness for about half an hour. It was also reported that she had somnolence, a headache and febricula since the fall occurred. Since Sunday (17-MAY-2009) injection site was a little swollen with some redness. The patient received ibuprofen to treat the adverse events (start and stop dates had not been reported). The events were not considered serious by the reporter. The reporter was contacted again on the 22-MAY-2009. He reported that the patient was almost completely recovered from the injection site inflammation but she continued with a headache. A CAT scan had not been realized yet. After internal review, the case was upgraded to serious. Other business partner numbers included: E2009-04284. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: WOLFF-PARKINSON-WHITE syndrome

Prex Illness:

Prex Vax Illns:

Vaers Id: **348313-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	22-Jun-2008	28-Jun-2008	6	02-Jun-2009	03-Jun-2009	FR	WAES0905HUN00008	11-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Collagen disorder, Cushings syndrome, Joint stiffness, Polyarthritis

Symptom Text: Information has been received from a physician concerning a 27 year old female weight not reported, healthy, was administered all 3 recommended dosages of GARDASIL for cervical cancer due to HPV infection prevention, on following dates 22-JAN-2008, 22-MAR-2008 and 22-JUN-2008, respectively. On 28-JUN-2008 the patient experienced latrogenic Cushing syndrome and poly-arthralgia (generalized joints pain) post vaccination. After about one week after the last administration dose of GARDASIL, the patient presented clinical signs of poly-arthritis that required hospitalizations and deeply investigations. Hospitalization periods and performed investigations were not provided by the physician. There were several hospitalization periods in different hospitals for investigations and starting treatments. After the performed investigations in the hospital, the clinical status was considered for diagnosis of non differentiated (unspecified) collagenosis for which treatment with MEDROL, calcium, vitamin D, VIGNEFOL, SPIRONOLACTONE, PIAQUENIL was administered. The dosages and periods of administrations were not provided. The evolution was slightly favorable. In present the general status of the patient was good with remission in proportion of 98% of the clinical symptomatology. A mild stiffness at the small joints was still persisting. At the time of the report the patient had not recovered. The reporting physician considered the adverse events of latrogenic Cushing syndrome and poly-arthralgia (generalized joints pain) post vaccination to be related to GARDASIL based on the discharge diagnosis from the hospital. The prophylaxis with GARDASIL was performed with all the recommended administrations- 3 dosages. There can not be discussion about action taken for interrupting, permanently discontinuing or continuing the prophylaxis treatment. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **348314-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jul-2007	23-Jul-2007	0	02-Jun-2009	03-Jun-2009	FR	WAES0905USA03951	03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Circulatory collapse, Loss of consciousness, Syncope

Symptom Text: Case received from a healthcare professional in a foreign country on 26-MAY-2009. This case is poorly documented. It was reported by a general practitioner that a 15 year old female patient was vaccinated with the first dose of GARDASIL (lot number, injection route and site not reported) on 23-JUL-2007. Approximately 2 hours post vaccination, the patient developed unconsciousness. The patient was hospitalized twice on an unspecified date. Diagnoses were vasovagal syncope and circulatory collapse. Findings (no otherwise specified) showed normal results. The outcome was not reported. A blood sample taken by the reporter on an unknown date showed increased IgE (no value reported). Other business partner numbers include E2009-04400.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, IgE increased (no value reported); Diagnostic laboratory test, findings (no otherwise specified) showed normal results

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **348315-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Jun-2009	03-Jun-2009	FR	WAES0905USA03954	03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Breast discharge, Breast swelling

Symptom Text: Information has been received from a gynaecologist on 26-MAY-2009. It was reported that a female adolescent patient (exact age at onset not reported) was vaccinated with a first dose of GARDASIL (Lot #, injection route and site not reported) on an unspecified date. Two days p.v., the patient developed swelling of the breasts with secretion. The patient was hospitalized on an unspecified date. Prolactin was normal, otherwise normal findings (not otherwise specified). The patient did not take any oral contraceptive. The patient recovered within an unspecified time. Other business partner numbers included E2009-04406. No further information is available.

Other Meds: Unknown

Lab Data: Serum prolactin test, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348323-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	28-Apr-2009	28-Apr-2009	0	02-Jun-2009	03-Jun-2009	FR	WAES0905MEX00018	03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic shock

Symptom Text: Information has been received from a physician concerning a female who on 28-APR-2009 was vaccinated with GARDASIL first dose. On 28-APR-2009 the patient experienced anaphylactic shock (details not reported). The outcome and causality were not reported. Upon internal review anaphylactic shock was considered other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348341-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jun-2009	01-Jun-2009	0	02-Jun-2009	03-Jun-2009	MO		10-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3098AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Presyncope

Symptom Text: Headache and dizziness s/p Tdap and HPV #3. Immunization given at 1515, gradual onset of headache over course of the day. Patient to ED at 2205 6/8/09 Received ER medical records 6/2/2009. FINAL DX: Headache & dizziness Records reveal patient experienced HA, lightheadedness, feeling like going to pass out approx 4 hrs s/p vaccination. Improved while in ER w/o treatment & d/c to home.

Other Meds:

Lab Data: unknown

History: PMH: fainting w/immunizations. Acne on doxycycline. Allergic rhinitis.

Prex Illness: none noted

Prex Vax Illns:

Vaers Id: **348352-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jun-2009	02-Jun-2009	1	02-Jun-2009	03-Jun-2009	CA		23-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	2	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3068AA	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Headache, Loss of consciousness, Pyrexia, Syncope

Symptom Text: My daughter fainted and was taken to the ER to be monitored, after going home she began with a fever... this is the day after receiving her rd HPV shot... not sre what other symptoms may arise... too soon to tell. 7/21/09 ER records received DOS 6/2/09. Assessment: Transient loss of consciousness. Patient presents with syncope. Was taking hot shower and felt light headed. Fell, took about 60 seconds to be fully alert, had not eaten. Headache. Dizziness and loss of consciousness.

Other Meds:

Lab Data: 7/21/09 ER records received DOS 6/2/09. LABS and DIAGNOSTICS: Neutrophils 89.4% (H) Lymphocytes 4.8% (L). Urinalysis - Protein (+1), Bacteria Few, Mucous / Hyaline Casts / sediment Present. CHEM - Glucose 172 mg/dl (H). CT Brain - Normal.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348357-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-May-2009	18-May-2009	0	02-Jun-2009	03-Jun-2009	CA		03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	00564	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2827CA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Blood pressure decreased, Dizziness, Heart rate decreased, Presyncope, Sinus bradycardia

Symptom Text: After 3 vaccines given Pt c/o dizziness, fan on pt - cool cloth on forehead - B/P checked, decreased 88/46 -head of bed down - foot of bed elevated. Remained alert, oriented, c/o weak, MD notified -vital signs monitored B/P slowly rising - HR decreased 46 - Oxygen offered 0.5, sips of water offered - Pt remained less than 1 1/2 hrs monitoring vital signs. EKG done. Sinus brady/borderline per MD. Vasovagal episode - D/C home at 4:50 - B/P 107/60- HR 63 - Pt feels much better.

Other Meds: Ibuprofen for cramps monthly prn

Lab Data: EKG per MD order

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348359-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	21-May-2009	23-May-2009	2	02-Jun-2009	03-Jun-2009	IA		03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	0570X	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	U2815AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	AC52B039BA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain, Swelling

Symptom Text: Given Immunizations Thurs. PM 5/21/09, but didn't notice swelling & erythema until Saturday 5/23. Pt reports "extreme pain" Sat/Sunday but feels better today; denies being seen by physician. No treatment to arm. No fever.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348360-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-May-2009	21-May-2009	1	02-Jun-2009	03-Jun-2009	WI		03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Hypersomnia, Muscle spasms, Pyrexia

Symptom Text: 5/21/09 Midmorning patient developed a fever and sweats (soaked clothes), dizziness and felt like she would blackout if stood up. Also started menstrual period with cramps- took MIDOL. PHN recommended take TYLENOL for fever and call MD if symptoms persist. 5/26/09 phone call with patient- she felt it was a combination of the shot, cramps and MIDOL. Did not see medical provider. Slept all day and was fine.

Other Meds: SYNTHROID; CONCERTA

Lab Data: None

History: thyroid condition; Attention deficit disorder

Prex Illness: No

Prex Vax Illns:

Vaers Id: **348368-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Jun-2009	02-Jun-2009	1	02-Jun-2009	03-Jun-2009	AZ		03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Body temperature increased, Decreased appetite, Rhinorrhoea, Sneezing, Urticaria

Symptom Text: Day after HPV she was weak, T.100, decreased eating, hives runny nose & sneezing.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348389-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jun-2009	01-Jun-2009	0	02-Jun-2009	03-Jun-2009	NY		03-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Pt felt lightheaded & thinks she may have fainted (briefly) while sitting in chair 3-4 min. after HPV #3 inject.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348399-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Mar-2009	01-Apr-2009	28	03-Jun-2009	04-Jun-2009	FR	WAES0905USA03441	05-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anorexia, Asthenia, Cell death, Choluria, Hepatitis acute, Hepatitis viral, Hypergammaglobulinaemia, Jaundice, Lymphadenopathy, Lymphocytosis, Malaise, Mucosal discolouration, Odynophagia, Pyrexia, Rash erythematous, Vasculitis, Yellow skin

Symptom Text: Information has been received on 19-MAY-2009 through a Medical Services department from a health care professional concerning a 16 year old female with no medical history or allergies who on 04-MAR-2009 was administered the second dose of GARDASIL (batch number not reported, site and route not reported). It was reported that in early April, the patient started with symptoms that were compatible with an acute hepatitis: asthenia, febricula, anorexia... It was later on confirmed through a biochemistry test performed in late April. Serologies were all negative. Bilirubin levels were high. During the patient's first episode the glutamic oxaloacetic transaminase (GOT) levels rosed up to 500. Afterwards they dropped to 200. Later on the patient had another episode where the GOT rosed to 3000. The patient was diagnosed with an acute viral hepatitis. Test results were pending. The reporter considered that due to the lack of an evident etiology for this adverse event, and taking in account that the patient was a healthy girl, vaccination could be the cause of the hepatitis. According to the reporter, it was very unlikely for this to be an autoimmune disease. An Hepatitis C Polymerase Chain Reaction and Citomegalovirus test had been ordered. Last test was performed on the 18-MAY-2009. GOT 1000, bilirubin levels were almost normal. The patient has been hospital admitted (date not reported). It is informed that the patient will be discharged from hospital next week (exact date not specified). On 18-MAY-2009 the patient was asymptomatic. On the 22-MAY-2009 the hospital report was received from the health care professional: Reason of admittance: Jaundice. Medical history: No previous relevant pathological medical records. No known allergies. The patient's sister had an infectious mononucleosis 4 months ago with an acute hepatitis. The patient was not taking any medication and did not have toxic habits. The patient was currently being administered the GARDASIL vaccines, first dose was administered on the 02-JAN-2009 and the sec

Other Meds: None

Lab Data: diagnostic laboratory test, acute hepatitis confirmed; chest x-ray, no significant findings; abdominal computed axial tomography, no significant findings; activated coagulation time, ??Apr09, normal; examination of blood cell morphology, ??

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **348400-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		03-Jun-2009	04-Jun-2009	AR	WAES0905USA03655	04-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a female patient who was vaccinated with GARDASIL when she was on her first trimester gave birth to a healthy baby but the baby was born without arms and legs. Lot # is not available. The patient had sought physician for medical attention. No further information provided at the time of reporting. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **348401-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		03-Jun-2009	04-Jun-2009	--	WAES0905USA04021	04-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a registered nurse who heard from another contact concerning a 22 year old female patient who was vaccinated with a dose of GARDASIL. After receiving vaccine, the patient experienced multiple sclerosis. The nurse stated that this was not one of their patients. At the time of reporting, the outcome was unknown. The patient sought unspecified medical attention. Attempts to verify the existence of an identifiable patient has been unsuccessful. Upon internal review, multiple sclerosis was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **348402-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	15-Dec-2008	01-Jan-2009	17	03-Jun-2009	04-Jun-2009	FR	WAES0905USA04115	04-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Brachial plexopathy, Mobility decreased, Muscular weakness, Nerve conduction studies, No reaction on previous exposure to drug, Pain in extremity, Paresis

Symptom Text: Information has been received from a 23 year old female pharmacist with history of frequently upper respiratory tract infections that she was vaccinated with a second dose of GARDASIL (Lot # and injection route not reported) into the left upper arm on 15-DEC-2008. On an unspecified date in January 2009, the patient experienced severe pain in the right arm, with weakness and decreased mobility. In May 2009, a neurologist diagnosed a right arm plexus paresis. A nerve conduction velocity had been carried out (not otherwise specified). Treatment with vitamin B and physiotherapy was recommended by the neurologist. At the time of reporting, the patient had not yet recovered. Concomitant therapy included hormonal contraceptives (unspecified). A third dose of GARDASIL was administered into the left upper arm in April 2009. It was well tolerated. The first dose of GARDASIL administered on 13-OCT-2008 into the left upper arm was well tolerated. Brachial plexus lesion was considered to be an other important medical event. Other business partner numbers include E200904450.

Other Meds: Hormonal contraceptives (unspecified)

Lab Data: Unknown

History: Upper respiratory tract infection

Prex Illness:

Prex Vax Illns:

Vaers Id: **348403-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-May-2009	12-May-2009	0	03-Jun-2009	04-Jun-2009	FR	WAES0905USA04118	04-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Tonic clonic movements

Symptom Text: Initial information was received on the 25-May-2009 by the foreign Health Authority (reference number ES-AGEMED-813211338). Information has been received from a physician concerning a 13 year old female patient (weighing 54 kilograms) with a history of dermatitis atopic who on 12-MAY-2009 was vaccinated with the first dose of GARDASIL vaccine by intramuscular route (site of administration not reported). There was no concomitant medication. Immediately after vaccine administration, the patient presented with an episode of tonic clonic movements and loss of consciousness for 3 to 4 seconds. The episode was self-limiting and the patient recovered spontaneously within a few minutes, no medication was used to treat adverse events. There were no personal nor family records of convulsive disorders. On the 01-MAY-2009 the patient took HIBITANE on her own. It hasn't been reported whether the patient presented any adverse event after this administration or not. It's reported that the physician that reported this adverse event had come across similar experiences after the administration of other vaccine. The reporter believed that these adverse events were related to the route of administration (intramuscular) rather than with the vaccine itself. Reported as serious by the HA with other medically important condition as criteria. Other business partner numbers include: E2009-04460. Case is closed.

Other Meds: None

Lab Data: Unknown

History: Dermatitis atopic

Prex Illness:

Prex Vax Illns:

Vaers Id: 348418-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Aug-2008	20-May-2009	273	03-Jun-2009	05-Jun-2009	--		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0135X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Asthenia, Blood pressure abnormal, Brachial plexopathy, Chest pain, Diarrhoea, Dizziness, Eructation, Fatigue, Gastrooesophageal reflux disease, General physical health deterioration, Headache, Lethargy, Long thoracic nerve palsy, Migraine, Muscular weakness, Musculoskeletal pain, Nausea, Neuralgic amyotrophy, Pain in extremity, Palpitations, Paraesthesia, Presyncope, Sensation of heaviness, Soft tissue neoplasm, Thyroiditis acute, Toothache

Symptom Text: The date above is simply the most recent event, one of many throughout the past 9 months. This date reflects the diagnosis given by a neurologist of Parsonage Turner syndrome, a rare neurological syndrome which impairs her left arm and shoulder which she first noticed with chest, arm and shoulder pain in March. It has left her left arm and shoulder weak. Her left scapula is markedly bigger and different than her right. My daughter received her first GARDASIL shot in August, right before she left for college. Within two weeks she began having loose bowel movements, fatigue, and complaining of her "legs feeling heavy". She is a runner and was in excellent physical condition. By early October, she had her thyroid levels tested. Normal levels are between 0.5 and 4.5. Her level was 24 leaving extremely fatigued. By the time I got her home and seen by her own physician the levels had dropped dramatically and seemed to have remain now in the normal level. This "acute thyroiditis" is caused by a "virus". Shortly thereafter, she began have dizzy spells, nausea, near fainting spells, often but not exclusively concurring in the middle of the night while lying down heart racing and dysregulation of blood pressure. Along with nausea she had and continues to have burbing/acid reflux symptoms. She was hospitalized by a cardiologist and they found nothing wrong with her heart. They did try her on a bp regulation medication-FLORINET-which seem to make things worse not better. She was referred to and electro physiologist, who met with her but only recommended that she continue to monitor her bp. She had tingling in her face and arms, toothache, nausea - which she has-, migraine like headaches, and then most recently the diagnosis of Parsonage Turner syndrome. Most of these symptoms came and went...the dizzy spells lasted for about 3 months, the headaches have not occurred since April. The Nausea continues as does the tingling in her left hand and left arm weakness. Her stamina is not what it used to be. She tires easily. 7/27/0

Other Meds: not known. 8/4/09 PCP medical records received DOS 8/20/08 to 10/25/08. Etodolac, multivitamin with iron. Fish oil. Synthroid.

Lab Data: EKG; Echo cardiogram; Blood work; Chest x ray, done with nothing notable seen; Blood work for thyroid levels were done and were elevated but have since dropped and remained normal; Lyme's blood work was done and and results were negative. M

History: My daughter was a healthy teen female with stable weight over her high school years. She was a runner who competitively raced and took remarkably good care of herself, ate well and exercised regularly. Her medical history was remarkable only for a history of strep throat and resulting tonsillectomy and adnoidectomy at age 10 and a knee injury from a bike accident after her sophomor

Prex Illness: Achilles tendinitis.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348424-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jun-2009	01-Jun-2009	0	03-Jun-2009	04-Jun-2009	MI		04-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B040AB	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	02944	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Nausea, Vomiting

Symptom Text: Nausea, vomiting, fatigue.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348425-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-May-2009	18-May-2009	0	03-Jun-2009	04-Jun-2009	NY		24-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C277BBA	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Abdominal pain, Abdominal pain upper, Asthenia, Chest pain, Cold sweat, Depressed mood, Dizziness, Fatigue, Feeling hot, Hypersensitivity, Immediate post-injection reaction, Limb discomfort, Lymphadenopathy, Malaise, Muscular weakness, Myalgia, Nausea, Pain in extremity, Pyrexia, Vomiting

Symptom Text: I took my daughter to a physician she had never been to before. While we were there the nurse suggested my daughter get the GARDASIL injection. I asked her 2 X's what are the side effects of this injection and she said only a slight chance of redness and swelling at the injection site. The Dr came in and AGA IN I asked her about ANY side effect of the GARDASIL, shot and she assured me that there was SIDE EFFECT. I said yes IF you ARE SURE there is NO CHANCE of any side effects.. 3 times I asked her BEFORE the injection. As soon as my daughter got the shot within SECONDS she felt sick. She became hot and clammy. At the check out desk at the Dr's, she felt very weak and dizzy..I asked the receptionists to call back and tell the Dr how my daughter was feeling, the Dr said it would pass. Within 10 minutes after the shot my daughter had extremely bad leg pain on the right side and could not walk. When we got home she felt very SAD and tired. During the night my daughter started throwing up. I called the ER and they said that that was not a normal reaction to an injection. That was Monday night, today is Wednesday and she still is having A LOT of symptoms and problems including muscle weakness, feeling sick, nauseous, chest pain, swollen glands, stomach pain. She went for blood work today and tomorrow a visit to the Dr who gave her the shot. This is CRAZY, she is suffering for what reason???? Because a Dr gave an injection WITHOUT either knowing- ignorantly-what can happen as a side effect on just not TELLING us. THIS MEDICATION SHOULD BE REMOVED..I my daughter should continue to suffer ANYTHING from this injection the makers will be SUED by US. 6/9/09 Medical records received DOS 5/18/09 to 5/20/09. Pt in for 14 yr WCC with 2-3 c/o coughing congestion. Vax given. Returned next day with c/o arm not feeling right since injections. Returned again 5/21/09 with c/o myalgias, abdominal pain and R-sided (illegible) pain and feeling ill since vax. PE . T=99.9. Assessment: Allergy. Myalgia. H/A. ? reaction to Gardasi

Other Meds: 6/9/09 Medical records received DOS 5/18/09 to 5/20/09. Tylenol

Lab Data: 6/9/09 Medical records received DOS 5/18/09 to 5/20/09. LABS and DIAGNOSTICS: Urine - blood (+) CBC - Lymph 30.1% (L) ALT 28 U/L (L) Results Pending: C3, C4, Insulin Level. 6/22/09 Labs received: C3 131 (N), C4 30 (N), Insulin 3 (N).

History: 6/9/09 Medical records received DOS 5/18/09 to 5/20/09. PMH: legally blind R eye.

Prex Illness:

Prex Vax Illns:

Vaers Id: **348433-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	29-May-2009	29-May-2009	0	03-Jun-2009	04-Jun-2009	OH		04-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Headache, Syncope

Symptom Text: I felt intense headaches and fainted and had a seizure.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **348434-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	23-May-2009		03-Jun-2009	04-Jun-2009	--		04-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Headache, Musculoskeletal stiffness, Myalgia, Neck pain, No reaction on previous exposure to drug

Symptom Text: About 5 hours after receiving the third of three injections of GARDASIL, I began to experience intense muscular pain and headache which continued for about 24 hours. After that time the majority of muscle pain subsided, although my lower back and neck - particularly the levator scapulae- were still sore and stiff. I did not experience any adverse side effects after the first two injections of GARDASIL

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **348435-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
34.0	F	07-May-2007	25-Nov-2008	568	03-Jun-2009	04-Jun-2009	MA		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0314U	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adverse drug reaction, Anal pruritus, Arthralgia, Chemotherapy multiple agents systemic, Decreased appetite, Diarrhoea, Fatigue, Hodgkins disease, Hypoaesthesia, Inappropriate schedule of drug administration, Lymphadenopathy, Muscular weakness, Musculoskeletal discomfort, Night sweats, Pyrexia, Rectal fissure

Symptom Text: Close to 9 months after being given the GARDASIL vaccine. I had a ct scan done, which showed that my lymph nodes were enlarged. A little over a year later. I was diagnosed with Hodgkin's Lymphoma -HL-. I am now undergoing chemotherapy treatment for this illness. This vaccine needs to be researched properly. I am convinced there is an increased risk for Lymphoma in women who were vaccinated. How many people have to die or get seriously sick for this vaccine to be investigated? I known of several women who became sick with Lymphoma months following vaccination with GARDASIL. I do not believe this is a mere coincidence. Statistical data would prove a connection, I'm certain. No oncologist or other doctor has ever asked me whether I was vaccinated with GARDASIL. 6/15/09 Oncology records received DOS 12/23/08 to 5/5/09. FINAL DIAGNOSIS: Hodgkin's Disease Lymphocytic Depletion, Unspec Site. Presented with complaints of fever and swollen cervical lymph nodes. Fatigue, pain/discomfort right neck. Night sweats. Decreased appetite. Muscle weakness and soreness in joints. Numbness right hand. Peri-anal itching, diarrhea, rectal fissure pain. Undergoing six cycles of chemotherapy. Has chemotherapy related side effects. ICD-9 Code: 201.70 6/19/09 PMH records received. PMH: Appy, ankle fx, ovarian cyst, blocked duct, UTI. 6/24/09 Medical, vaccine records received. DOS 4/23/07 to 5/17/07. Medical records consist of laboratory studies only.

Other Meds:

Lab Data: 6/15/09 Oncology records received DOS 12/23/08 to 5/5/09. LABS and DIAGNOSTICS: CT Scan - paratracheal, pretracheal and prevascular lymph nodes. Nodules in lungs. MRI Brain - WNL. PET - involvement in mediastinal, pretacheal, and cervical

History: 6/19/09 PMH records received. PMH: Appy, ankle fx, ovarian cyst, blocked duct, UTI.

Prex Illness:

Prex Vax Illns:

Vaers Id: **348469-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	31-Dec-2008	18-Mar-2009	77	04-Jun-2009	08-Jun-2009	AZ		08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MMR	MERCK & CO. INC.	1369X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0575X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Pt denied being preg. 12/31/08. Had US on Feb'2009 and was informed baby had problems and abortion done 3/18/09 at OB.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 348475-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Jun-2009	03-Jun-2009	0	04-Jun-2009	08-Jun-2009	IN		17-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2686AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC528029AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Concussion, Convulsion, Crying, Dizziness, Dyskinesia, Emotional distress, Head injury, Hypoaesthesia, Loss of consciousness, Post-traumatic headache, Swelling, Syncope, Visual impairment

Symptom Text: RECIEVED TDAP, GARDISIL, MENINGOCOCCAL INJECTION, TOLERATED WELL, WALKED OUT OF EXAM ROOM AND PASSED OUT (5 -7 MINUTES AFTER INJECTIONS) 6/10/09 Hospital records received DOS 6/3/09 to 6/4/09. FINAL DIAGNOSIS: Syncope, closed head injury. Post vaccination patient passed out, hit back of head, had brief jerking activity. Emotional, crying, headache, left hand numbness. Nausea, visual changes, lightheaded. Tenderness, swelling over occiput. 7/16/09 ICD-9 Codes: 780.2, 959.01, 784.0, 780.4

Other Meds:

Lab Data: TO EMERGENCY ROOM FOR EVALUATION. 23 HOUR OBSERVATION IN HOSPITAL, CONCUSSION.CT HEAD. 6/10/09 Hospital records received DOS 6/3/09 to 6/4/09. LABS and DIAGNOSTICS: Head CT (-). CBC, metabolic panel unremarkable.

History: ACNE, BACK-MILD

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **348485-1** **Related reports:** 348485-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Jun-2009	01-Jun-2009	0	04-Jun-2009	08-Jun-2009	CA		15-Jun-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2683AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1005X	0	Right arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Dyskinesia, Fall, Hypotension, Hypotonia, Hypovolaemia, Loss of consciousness, Lumbar puncture, Mental status changes, Pallor, Pyrexia, Syncope, Tonic clonic movements, Urinary incontinence, Viral infection

Symptom Text: Approx 5 min after receiving immz, pt appeared to have a seizure; loss of consciousness <45 seconds, jerky movements, urinated on self. Ammonia inhalant used, pt. conscious, pale color, O2 given-approx after 1 minute pt AOX3. However, approx in the next 3 minutes pt again appears to have another seizure in the same manner as above, lasting approx <45 seconds. 911 called, pt stabilized and transported to ER. I spoke with the parent the next day and she advises that they discharged her and diagnosed her as having a seizure and the follow up; the parent advised she will follow up. 6/10/09 Received ER medical records of 6/1/2009. FINAL DX: acute syncopal episode, mild volume depletion Records reveal patient experienced altered mental status x 2 episodes, dizziness, hypotonia & orthostatic collapse w/fall, tonic-clonic seizure-like activity, urinary incontinence. Was hypotensive in ER. Tx w/IVF, improved & d/c to home w/PCP f/u. Returned to ER on 6/2/09. FINAL DX: Fever, viral syndrome. Experienced low-grade fever. Tx w/IV antibiotic. LP performed.

Other Meds: unknown

Lab Data: Medical Center did lab work and CT scan, per parent unknown results. Medical records state LABS: CT head WNL.CBC, BMP & CSF tests WNL. CSF c/s neg.

History: None known of. Parent advises no previous adverse signs and symptoms with immunizations.

Prex Illness: None known of.

Prex Vax Illns:

Vaers Id: **348485-2** **Related reports:** 348485-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Jun-2009	01-Jun-2009	0	08-Jun-2009	09-Jun-2009	CA		09-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	AC52B028AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U263BAA	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	1005X	0	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Balance disorder, Convulsion, Headache, Pyrexia, Syncope, Vomiting

Symptom Text: Pt had vaccines administered at Health Department on 6/1/09, within 5 minutes pt had syncope and seizure, lasted under 1 minute then pt had additional seizure. Pt transported to ER. CT normal. EEG pending. I saw pt on 6/2/09 (day after vaccines), she was not feeling steady, no fever. She was seen again in ER that night for headache vomiting and 100.3 fever per moms call. CT and Spinal tap done and reported as negative.

Other Meds: none

Lab Data: awaiting EEG CT scan and spinal tap

History:

Prex Illness: none known

Prex Vax Illns:

Vaers Id: **348487-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-May-2009	29-May-2009	0	04-Jun-2009	08-Jun-2009	CA		08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	HEPA
							TDAP

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Depressed level of consciousness, Loss of consciousness, Tonic clonic movements

Symptom Text: Was standing in line 5-10 minutes after the injection making an appointment when she lost conciousness and suffered tonic clonic movements for 30 seconds and then did not respond completely with alertered conciousness.

Other Meds: None

Lab Data: Normal EEG and Echocardiogram

History: None - local reaction to bee stings

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348488-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-May-2009	28-May-2009	1	04-Jun-2009	08-Jun-2009	CA		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, No reaction on previous exposure to drug, Swelling

Symptom Text: Given 3rd GARDASIL on 5/27/2009 - swelling/ redness started within 24 hours - seen 5/29/09 - treated with MOTRIN, BENADRYL. No previous Rxn to GARDASIL

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348490-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	28-May-2009	29-May-2009	1	04-Jun-2009	08-Jun-2009	PA		08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0162Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives all over body.

Other Meds: Nuvaring

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348550-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	02-Jun-2009	02-Jun-2009	0	05-Jun-2009	08-Jun-2009	LA		08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Cold sweat, Fall, Hearing impaired, Muscle rigidity, Musculoskeletal stiffness, Pallor, Somnolence, Tinnitus

Symptom Text: Approx 5 minutes after injection Pt became rigid all over, very stiff, and fell down to table. After several minutes then began to arise but was very groggy, clammy, pale and c/o ringing ears and could not hear. BP decrease 80/50.Watched and monitored over 30 minutes which at which time was lunching and felt better and released to home with mother. 12:45PM called Pt to check on her and mom states was doing very well.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348552-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-May-2009	29-May-2009	0	05-Jun-2009	08-Jun-2009	AZ		08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Nausea, Syncope, Vomiting

Symptom Text: Pt was injected with 2nd GARDASIL inj. About 30 seconds later pt fainted fell head first off of bed. Pt hit right forehead on floor and ice was applied. Pt became nausea and vomited. Pt was sent to Hospital for evaluation.

Other Meds: Trinessa 28d Birth Control

Lab Data: UA; UOS; CT head/brain w/o contrast, Chest

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348554-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-May-2009	29-May-2009	2	05-Jun-2009	08-Jun-2009	LA		08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF451AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2910AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site cellulitis, Injection site urticaria

Symptom Text: 9 cm X 5cm red whelp to (R) deltoid, not tender to touch, cellulitis. Treatment - BACTRIM DS

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348559-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-May-2009	27-May-2009	0	05-Jun-2009	08-Jun-2009	NJ		25-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2872AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Urticaria on arms / legs about 1 hour after receiving,MENACTRA, HPV #1, HEP A #1, on 5/27/09 no other complaint.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348568-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	27-Mar-2009	30-Apr-2009	34	05-Jun-2009	08-Jun-2009	FR	WAES0905TUR00004	08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Fibrin D dimer increased, Pulmonary embolism

Symptom Text: Information has been received from a physician concerning a 25 year old female with oral contraception who on 27-MAR-2009 was vaccinated with GARDASIL. Concomitant therapy included JASMINE for 4 months. On 30-APR-2009 the patient experienced pulmoner emboli and was hospitalized. On the angiography, there was pulmoner emboli in dextra inferior lob; invasive lesions in sinistra. D-dimer value was 1800 microgram/ml. Subsequently, on 6th May 2009 the patient recovered from pulmoner emboli. On 16th of May 2009 the patient was discharged from hospital. The reporter felt that pulmoner emboli was not related to therapy with GARDASIL. Therapy with human papillomavirus was discontinued. Pulmoner emboli was considered to be immediately life-threatening. Additional information is not expected.

Other Meds: Unknown

Lab Data: angiography, 06May09, 1800 MICROGRAM/ML

History:

Prex Illness: Oral contraception

Prex Vax Illns:

Vaers Id: **348569-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		05-Jun-2009	08-Jun-2009	--	WAES0905USA03885	08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Electrocardiogram QT prolonged, Torsade de pointes

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (Lot # not provided). The physician reported that the patient experienced long QT interval and torsade de pointes after getting the vaccine. At the time of reporting the outcome of the event was unknown. The patient sought medical attention. Upon internal review torsade the pointes was considered to be an other important medical event. This is an amended report. The adverse event Torsade de Pointes was added in the AE info screen as other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: electrocardiogram, long QT interval

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **348571-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	29-Jan-2009		05-Jun-2009	08-Jun-2009	FR	WAES0906USA00369	08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ataxia, Gait disturbance, Hiccups, Myoclonus

Symptom Text: Information has been received from a health authority concerning a previously healthy 17 year old female patient who was vaccinated with two doses of GARDASIL (lot #, injection route and site not reported) on not assignable dates (written as "11/7" and "2/8" in the reporting form). On 29-JAN-2009 she developed segmental myoclonus, ataxia, gait disorder and singultus. The patient has not recovered at the time of reporting. Segmental myoclonus, ataxia, gait disorder and singultus were determined to be other important medical events. Other business partner's numbers included: E2009-04330 and PEI2009010690. Further information was requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **348572-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		05-Jun-2009	08-Jun-2009	FR	WAES0905CAN00098	08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bone disorder

Symptom Text: Information has been received from a physician concerning a 14 year old female who was vaccinated with the third dose of GARDASIL, lot # not available. Subsequently the patient developed "the bones of an 80 year old" and was hospitalized. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 348607-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Jun-2009	04-Jun-2009	0	05-Jun-2009	08-Jun-2009	--		08-Jun-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0653X	2	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2662AA	2	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3097AA	5	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB258AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Headache, Hypotension, No reaction on previous exposure to drug

Symptom Text: 06052009@9:16am MOC t.c. c/o mild dizziness 1 hours post vaccinations then severed ha, lbp and dizziness with falling this morning on ambulation. had previous HPV vaccinations w/o issue, suspect menactra but referred to pmd for evaluation of any possible underlying medical conditions prior to this conclusion for patient safety and care. MOC stated verbal understanding of instruction and will call pmd immediately. per MOC pt is not suffering any breathing or chest pain currently but is aware to take to ER immediately if it occurs, MOC stated verbal understanding.

Other Meds: nothing per MOC

Lab Data: pending with pmd

History: nothing per MOC

Prex Illness: no per moc

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348652-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	04-Jun-2009	05-Jun-2009	1	05-Jun-2009	08-Jun-2009	CA		08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF486DA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea

Symptom Text: Shortness of breath and dizziness

Other Meds:

Lab Data:

History: none

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348676-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-May-2009	27-May-2009	1	08-Jun-2009	08-Jun-2009	OR	OR200923	08-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2875AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	00424	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling, Pyrexia

Symptom Text: Has hard, red swollen area at one injection site (believes to be varicella) running fever. (Right arm site of injection).

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348678-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Jun-2009	03-Jun-2009	0	08-Jun-2009	09-Jun-2009	PA		09-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130K	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Dizziness, Fall, Gaze palsy, Immediate post-injection reaction, Syncope

Symptom Text: Immediately following administration of GARDASIL she was sitting on exam table, felt lightheaded and fainted. falling to floor. Mother in room reported patients eyes rolled back - immediately was awake & alert to place - Right hip sore from fall. Had normal vital signs. Rested , drank fluids & went home within 30 minutes

Other Meds: None

Lab Data: None

History: Overweight

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348682-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-May-2009	28-May-2009	0	08-Jun-2009	09-Jun-2009	GA	WAES0906USA00554	09-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294Y	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female with a history of convulsions and under the care of an unspecified neurologist who was vaccinated with the first (lot # 0947X), the second (lot # 1423X) and the third (lot # 0294Y) dose of GARDASIL (IM, 0.5ml) on 28-NOV-2008, 28-JAN-2009 and 28-MAY-2009 respectively. Concomitant therapy included Yaz. On 28-MAY-2009 the patient "fainted and then went into convulsions" immediately after receiving her third dose of GARDASIL. The patient roused after 60 seconds and was fully recovered within 1 hour. The patient did not have lab diagnostics studies performed. The patient did not experience adverse symptoms after the first and second dose of GARDASIL. Follow-up information has been received from a medical assistant who stated that the patient did not receive any concomitant vaccines when she received the GARDASIL. The reporter stated that the patient was on the exam table when she fainted and went into convulsions. The nurse was able to lay the patient down on the exam table. The reporter stated that the patient's neurologist was not documented in the patient's chart. Upon internal review, convulsions was determined to be an other important medical event. Additional information has been requested.

Other Meds: Yaz

Lab Data: None

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vaers Id: 348684-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Dec-2007	01-Dec-2007	0	08-Jun-2009	09-Jun-2009	--	WAES0906USA00298	24-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0825U	3	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal injury, Abdominal pain, Abdominal pain upper, Accident at home, Anxiety, Cervical discharge, Cervix dystocia, Chest discomfort, Contusion, Cough, Dysmenorrhoea, Dyspnoea, Dysuria, Ecchymosis, Face injury, Inappropriate schedule of drug administration, Infertility female, Leukocytosis, Menstruation irregular, Muscle spasms, Musculoskeletal chest pain, Nausea, Neck pain, Ovarian cyst, Pelvic pain, Pyrexia, Respiratory fume inhalation disorder, Tobacco abuse, Urinary tract infection, Victim of crime, Vomiting

Symptom Text: Information has been received from a 17 year old female with no medical history or drug allergy who was vaccinated with 1st, 2nd and 3rd doses of GARDASIL in April 2007, October 2007 and December 2007, respectively. There was no concomitant therapy. In December 2007, after receiving the third dose of GARDASIL, the patient experienced irregular periods and severe pain during menstruation. She was hospitalized on 01-JAN-2008 and informed that she had cysts in her ovaries and she would no longer be able to conceive. The doctor advised her that GARDASIL had caused these problems. She was not recovered at time of reporting. The patient went to hospital for medical attention. Additional information is not expected. 6/12/09 Medical records received DOS 2/7/08. Referred to OB-GYN for management of ovarian cyst. 7/23/09 Hospital records received, consist of multiple ER visits, DOS 6/25/08 to to 4/18/09. Assessment: Anxiety Attack, Chest Wall Pain, Tobacco Abuse Disorder. Urinary Tract Infection. Smoke Inhalation. Facial contusion, chest wall contusion. Patient presents with shortness of breath and chest discomfort, anxiety. Pelvic pain and cramping, distressed. Inside burning home, cough, smoke inhalation. Dysuria, distressed, UTI. Assault, hit in face and abdomen, face pain, ecchymosis, neck pain. Abdominal pain, nausea, vomiting, fever, leukocytosis, cervical tenderness on motion, purulent discharge from cervix. Epigastric pain. ICD-9 Codes: 786.50 300.00 786.52 305.1 465.9 789.00 786.09 987.9 E890.2 786.05 599.0 V71.6 920 922.1 E960.0 288.60

Other Meds: Unknown

Lab Data: Unknown. 7/23/09 Hospital records received DOS 6/25/08 to to 4/18/09. LABS and DIAGNOSTICS: Urinalysis - Cloudy, 25-50 WBC's, 2-5 RBC's, 1+ Epithelials, 4+ Bacteria, Culture Ordered. CBC - WBC 15.8 10^3/uL (H) Lymph 12.4% (L) Eosin 10.6% (

History: Unknown. 6/12/09 Medical records received DOS 2/7/08. History of heart murmur and ovarian cyst. 7/23/09 Hospital records received DOS 6/25/08 to to 4/18/09.PMH: Asthma, tobacco use.

Prex Illness:

Prex Vax Illns:

Vaers Id: **348696-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-May-2009	19-May-2009	0	08-Jun-2009	09-Jun-2009	FR	WAES0906USA00370	09-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Mydriasis, Syncope

Symptom Text: Initial information received from the Health Authority (reference number ES-AGEMED-921102341) regarding a 14 year old female who was administered on 19-MAY-2009 a dose of GARDASIL (Lot not reported) by intramuscular route. On the same date of vaccination, 19-MAY-2009, the patient lost of consciousness, had a syncope, and presented dilated pupils. She recovered from all these events in 15 minutes. Case reported as serious by the HA with other medically important condition as criteria. Other business partner numbers include: E2009-04579. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **348701-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Jun-2009	04-Jun-2009	1	08-Jun-2009	09-Jun-2009	IA	IA090006	16-Jun-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0049Y	1	Right arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2663AA	0	Right arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB706AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0652X	0	Right arm	Unknown	
HEPA	MERCK & CO. INC.	1605X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth, Nausea

Symptom Text: Reddened, raised, tender, warm to touch area approx 2" x 3" at Varicella injection site. T. 99.3. C/o slight nausea, seen in our Public Health Office at 10 AM 6-5-09. Recovered cold to site and TYLENOL or MOTRIN as directed. Phone call on 6-8 reports much improved.

Other Meds: None

Lab Data: None

History: Allergy to; Pertussis, PENICILLIN, AMOXICILLIN

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348710-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	05-Jun-2009	05-Jun-2009	0	08-Jun-2009	09-Jun-2009	FL		09-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB281BB	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	2	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall

Symptom Text: I ASSESSED A 12 YEAR OLD FEMALE WHO WAS ALERT AND ORIENTED. THE MOTHER STATED THAT THE CHILD WAS DUE HER LAST HPV SHOT AND THERE WAS NO PROBLEM WITH THE LAST TWO DOSES. I ASKED IF THE CHILD WAS WELL TODAY, MOTHER REPLIED SHE WAS ALRIGHT. I PROCEDED TO ADMINISTER THE VACCINES. THE CHILD SAID SHE WAS FINE AFTER RECEIVING THE VACCINES. THE CHILD SAT WITH HER MOTHER STANDING CLOSE BESIDE HER AS I COMPLETED HER PAPER WORK AND WAS INSTRUCTED TO INFORM ME OF ANY CHANGES(DIZZINESS, NAUSEA ETC). SHORTLY AFTER THE CHILD FELL TO THE FLOOR, MOTHER STATED SHE TAUGHT THE CHILD WAS PLAYING. DR. CAME AND ASSESS THE CHILD. NO INJURIES NOTED. THE MOTHER OF THE CHILD STATED THAT THE CHILD HADN'T EATEN ALL DAY EXCEPT TO DRINK A GLASS OF MILK. DR. INFORM MOTHER TO CONTINUE TO OBSERVE THE CHILD AT HOME AND ANY CHANGES TO TAKE THE CHILD TO THE EMERGENCY ROOM.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **348712-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-May-2009	20-May-2009	0	08-Jun-2009	09-Jun-2009	NY		09-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphonia, Injection site rash, Nasal congestion, Pain, Pyrexia

Symptom Text: fever, nasal congestion, lost voice, body aches, rash at injection site

Other Meds: unknown

Lab Data: None

History: psoriasis, seasonal allergies

Prex Illness: none

Prex Vax Illns:

Vaers Id: **348714-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Jun-2009	04-Jun-2009	2	08-Jun-2009	09-Jun-2009	CO		09-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1781X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0652X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site oedema, Injection site pain, Injection site warmth

Symptom Text: Varicella administered on Tuesday,6/2/09. On Thursday a 2.5 inch x 2 inch erythematous, raised, tender, area noted around injection site. This area was warm to touch. Denied fever, itching, streaking, or any other systemic symptoms. One tablet of Benedryl taken Friday night before bed. Woke up Saturday, 6/6/09 and less reddness and edema noted. Spoke with mother today, 6/8/09 and the area of erythema and edema has cleared. Area no longer tender.

Other Meds:

Lab Data:

History:

Prex Illness: Denies

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348726-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	25-May-2009	25-May-2009	0	09-Jun-2009	10-Jun-2009	--	WAES0906USA00012	10-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Information has been received from a consumer concerning his 24 years old fiancee who on 25-MAY-2009 received the first dose (0.5ml) of GARDASIL. There was no concomitant medication. On 25-MAY-2009 the patient experienced pins and needles feeling in her hands and tingling. The patient was admitted in hospital (name and address unspecified) for whole day of 26-MAY-2009. A GBS test was performed (results not reported). The patient's experienced pins and needles in her hands and tingling persisted. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 348727-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Nov-2008	14-Nov-2008	1	09-Jun-2009	10-Jun-2009	FR	WAES0906USA00371	10-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Dizziness, Educational problem, Electroencephalogram, Gingival swelling, Headache, Nasopharyngitis

Symptom Text: Information has been received from a Health Authority (HA reference number ES-AGEMED-221086341) concerning a 14 year old female with no pertinent medical history reported who on 13-NOV-2008 was vaccinated with a dose of GARDASIL (batch number not reported) by intramuscular route (site of administration not reported). The day after vaccine administration on 14-NOV-2008, the patient experienced started with frequent cephaleas and dizziness which lasted for hours, the patient presented with loss of vision in the right eye which she recovered in a half an hour. Also it was mentioned that the patient was having a lot of colds this winter and her gums were swollen (coded by the Health Authority as gingivitis). This had happened three times this year. The patient was getting catastrophic school grades. All of this started the day after vaccine administration. The patient brought several emergency rooms reports from health care centers and hospitals. An EEG was performed and the patient was sent home. At the time of reporting the patient had not recovered. The case was reported as serious by the Health Authority with other important medical conditions as criteria. Other business partner numbers included: E2009-04580. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **348728-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Apr-2009	16-Apr-2009	0	09-Jun-2009	10-Jun-2009	FR	WAES0906USA00412	10-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1049U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Henoch-Schonlein purpura, Myalgia, Petechiae

Symptom Text: Information has been received from a gynaecologist concerning a 13 year old female who was vaccinated with a first dose of GARDASIL (lot number not reported) intramuscularly in the left upper arm on 16-APR-2009. About four days post vaccination, on approximately 20-APR-2009, the patient developed muscle pain, redness and petechiae of both lower legs. After consultation of several physicians Schoenlein-Henoch purpura was diagnosed. The patient was not hospitalized and was treated with corticoid-containing ointments (not otherwise specified). She recovered completely within an unspecified time. Follow up information was received on 02-JUN-2009. The patient was vaccinated with dose one of GARDASIL (lot number 1049U, batch number NG46500) on 16-APR-2009. The same day, she developed muscle pain (not four days post vaccination, as reported initially). On 20-APR-2009, purpura emerged and the patient was diagnosed as Schoenlein-Henoch. Routine laboratory values (including CRP) were within the normal range. No information was given regarding the patient's previous history (e.g. infections). The symptoms disappeared completely within 14 days. Upon internal review Schoenlein-Henoch purpura and muscle pain were considered to be other important medical events. Other business partner numbers included: E2009-04481. Additional information has been requested.

Other Meds: Unknown

Lab Data: serum C-reactive protein, 20?Apr09, within normal limits

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 348729-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Jun-2007	01-Mar-2009	628	09-Jun-2009	10-Jun-2009	MI	WAES0906USA00536	02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Areflexia, Arthralgia, Asthenia, Blood product transfusion, Chronic inflammatory demyelinating polyradiculoneuropathy, Demyelination, Dysstasia, Fatigue, Influenza, Joint range of motion decreased, Muscular weakness, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on 14-NOV-2006, 16-JAN-2007 and on 12-JUN-2007 was vaccinated with the first, second and third doses of GARDASIL (Lot # not reported). It was reported that in "March 2009" the patient experienced weakness, pain in her legs and hips and the patient sought medical attention with the physician, then she was admitted to the hospital for three days on 07-APR-2009. It was reported that the patient was diagnosed with "acute demyelinating disease". The physician noted that the patient received gamma globulin for three days. It was reported that the patient was recovering but not fully recovered. The reporting physician considered "acute demyelinating disease" to be disabling. The Health Care Professional contacted during telephone follow up could not supply the following information: patient name and Lot numbers. Additional information has been requested. The patient was hospitalized. 8/14/2009 MR rec'd from PCP which includes Neuro consult in f/u to hospitalization with DX: CIDP/sub-acute polyradiculopathy. Pt developed fever, cough, cold sx, abdominal pain, H/A and stuffy ears 2/9/2009. Flu (+). Dx: Viral Flu. Returned 3/5/09 with c/o hip pain, numbness/weakness in both feet, muscle stiffness. Had recent knee injury. Worsening by 4/2/09 and referred to neurologist. Admitted 4/23-29 with dx CIDP. Tx IVIG. Neuro f/u 5/22/09 with almost complete resolution of sx. 9/1/09 Hospital records received DOS 4/23/09 to 4/29/09 and 5/21/09 to 6/21/09. Assessment: Chronic Inflammatory Demyelinating Polyneuropathy (possibly secondary to influenza illness) Patient presents with bilateral upper and lower extremity weakness, influenza diagnosed 2/10/09. Fatigue, bilateral hip and calf pain. Range of motion decreased in lower extremiities. Reflexes absent. Wide-based stance. IVIG. Improved.

Other Meds: Unknown

Lab Data: Unknown. 8/14/2009 MR rec'd from PCP. Labs and Diagnostics: EMG abnormal. CSF protein increased. 9/1/09 Hospital records received DOS 4/23/09 to 4/29/09 and 5/21/09 to 6/21/09. LABS and DIAGNOSTICS: CSF Culture - No Growth. CSF - Protei

History: Unknown 8/14/2009 MR rec'd from PCP. Allergy to Ceclor and tree nuts. 9/1/09 Hospital records received DOS 4/23/09 to 4/29/09 and 5/21/09 to 6/21/09. Asthma, T/A, myringotomy bilateral.

Prex Illness:

Prex Vax Illns:

Vaers Id: **348735-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Apr-2009	10-Apr-2009	1	09-Jun-2009	10-Jun-2009	FR	WAES0906USA00772	10-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0779X	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Localised oedema, Pruritus

Symptom Text: Information has been received from Health Authorities (reference number: N200905-558) concerning a 17 years old female with infection and contraception and a history of allergies to several substances until the age of 6 years old who on 09-APR-2009 was vaccinated with a first dose of GARDASIL (lot number 0779X and batch number NJ32820) via intramuscular route. On 10-APR-2009, one day after vaccination, she developed scalp and both knees pruritus, with oedema and articulation pain. The patient was sent to hospital where she was treated with antihistamines and corticosteroids. To be noted that she was concomitantly taking CEFACLOR per os since March 2009 for infection, and contraceptives per os since January 2008 with DROSPIRENONE and ETINILESTRADIOL. At the time of reporting, the outcome was unknown. Other company numbers included: E2009-04643. Additional information has been requested.

Other Meds: CEFACLOR, Mar09-Unk; DROSPIRENONE, Jan08-Unk.

Lab Data: Unknown

History: Multiple allergies

Prex Illness: Infection; Contraception

Prex Vax Illns:

Vaers Id: **348737-1** **Related reports:** 348737-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	16-Apr-2008	16-Apr-2008	0	09-Jun-2009	10-Jun-2009	MI		26-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain lower, Asthenia, Back pain, Endometrial hypertrophy, Flank pain, Hypoaesthesia, Keloid scar, Musculoskeletal discomfort, Neuropathy peripheral, Ovarian cyst, Pain in extremity, Pallor, Peripheral coldness, Poor peripheral circulation, Pulse absent, Renal atrophy, Renal hypertrophy, Thoracic outlet syndrome, Varicose vein, Venous insufficiency

Symptom Text: GARDASIL vaccine - neuritis (LUE) - thoracic outlet syndrome - no strength (L) arm/(R) arm (decrease strength)- decrease vasc (L) arm (with elevation - color pale/cool) (L) - left more than right. Hasn't changed or lessened for 2 years. 6/25/09 PCP records received DOS 5/4/09 to 6/15/09. Assessment: Arm numbness and pain post HPV vaccine. Patient states "feels like the blood is not in her arms." Pulses in arms disappear when in a military position. Intermittant RLQ pain, L flank pain, back pain, R rhomboid muscle region discomfort, keloid R ankle, Venous insufficiency with varicose veins L lower extremity. Retroverted uterus, thickening of endometrium, ovarian cysts. Congenital L renal hypoplasia, compensatory hypertrophy R kidney. Gardasil #1 (Lot# 1486U) LA - 4/16/08. Gardasil #2 (Lot# 1486U) RA - 6/16/08.

Other Meds: None

Lab Data: None. 6/25/09 PCP records received DOS 5/4/09 to 6/15/09. LABS and DIAGNOSTICS: Ultrasound Pelvis - Abnormal. Ultrasound Abdomen - Abnormal. Chest X-Ray - No abnormalities. CTA of abdominal aorta and renal ateries with CT of abdomen and pel

History: NKDA; No med conditions

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348737-2 (S)** **Related reports:** 348737-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	16-Apr-2008	17-Apr-2008	1	25-Jun-2009	26-Jun-2009	MI	WAES0906USA00886	26-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Cyanosis, Flank pain, Muscular weakness, Peripheral coldness, Pulse absent, Renal atrophy, Renal hypertrophy, Thoracic outlet syndrome, Vascular insufficiency

Symptom Text: Information has been received from a medical assistant and a registered nurse concerning a 26 year old female with no pertinent medical history reported and no known drug allergies who on 16-APR-2008 and 16-OCT-2008, was vaccinated intramuscularly with first 0.5mL dose (Lot number 659329/1468U, valid for Varicella virus vaccine live (MSD) and second 0.5mL dose (Lot number 660620/0571X), respectively of GARDASIL. There was no concomitant medication. The medical assistant reported that on 16-APR-2008, the patient developed thoracic outlet syndrome. It was reported that the patient had no strength on her left arm and right arm. She had decreased "vascular" in her left arm with elevation. The registered nurse reported that the patient came to the office. She reported that her arms felt like blood was draining out of them when she raised them and got blue and cold. The left arm had no strength and the right arm had little strength. The condition had not improve since the second dose of GARDASIL. The vaccine was given to the patient consecutively in alternating arms. The registered nurse reported that the physician was looking into other causes like conditions relating to her chest region because he did not believe that this event was related to GARDASIL. As of 04-JUN-2009, the patient had not recovered from the event. The patient sought unspecified medical attention. Follow up information was received from a registered nurse which revealed that no other vaccines were administered at the time of the three GARDASIL doses. No labs/diagnostic tests were ordered for Thoracic Outlet Syndrome. No consults were requested. It was reported that the physician told the patient to be caution when lifting or doing heavy work. The registered nurse also reported that on 04-JUN-2009, when the patient was seen for a pap smear (results not provided), she complained of right flank pain. An ultrasound of the abdomen and pelvis, performed on 08-JUN-2009, showed severe atrophy of the left kidney with compensatory hypertrophy of the right ki

Other Meds: None

Lab Data: Ultrasound, 06/08/09, severe athropy of left kidney, compensatory hyperthrophy of the right kidney

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Jun-2008	14-Jul-2008	35	09-Jun-2009	09-Jun-2009	OH		10-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2888AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Joint pain in arms & shoulders. Evaluated by Geneticist & Rheumatologist.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348763-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Jun-2009	01-Jun-2009	0	09-Jun-2009	09-Jun-2009	VA		10-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Per patient legs broke out in hives evening of injection 6/1/09. Woke up next AM & hives on arms & legs. Patient took 25 mg BENADRYL 8 AM on 06/02/09. Instructed to take 50 mg @ 12:30. On 6/3/09 mother was called & stated pt better went back to work

Other Meds:

Lab Data:

History: TYLENOL with CODEINE

Prex Illness: Bronchitis, Asthma exacerbation

Prex Vax Illns:

Vaers Id: **348772-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Jun-2009	02-Jun-2009	0	09-Jun-2009	10-Jun-2009	MA		10-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt fainted 5 min after 3rd GARDASIL injection - Had received injection then walked on to waiting area to get father. Fainted after return to exam soon.

Other Meds:

Lab Data:

History: Exercise induced RAD

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348788-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	12-May-2009	12-May-2009	0	09-Jun-2009	10-Jun-2009	DE		10-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1702X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dry throat, Injection site pruritus, Nausea, Pruritus

Symptom Text: Patient received #2 GARDASIL on 5-12-09 and called 5-15-2009 reporting c/o itching / have several hours after she had GARDASIL 5-12-09. Pt took Benadryl as suggested by pharmacist per Pt. (gel + tab Benadryl Pt received relief injection site itchy on 5-14-09. Also some nausea + throat got dry on 5-12-09 per pt.

Other Meds: Orthonovum 1/35, Metformin, Effexor XR, Nexium, Clarinex D.

Lab Data:

History: Asthma, Seasonal Allergies

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348790-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Jun-2009	08-Jun-2009	0	09-Jun-2009	10-Jun-2009	IA	IA090007	10-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2824AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1427F	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2938AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1748X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dreamy state, Feeling abnormal, Nausea, Pallor, Syncope

Symptom Text: Pt. stated stomach felt queasy; sat down; says her vision was fuzzy; became pale; fainted; assisted to a lying position et fanned; regained consciousness within 1-2 sec.; stated "felt like a dream"; sat up after 5 min. felt faint again; lost color again; laid back down; fanned; talked to staff and family; sat up again after 5min; ate snack good color; strong pulse; stood up - no problems; left.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	02-Jun-2009	02-Jun-2009	0	09-Jun-2009	10-Jun-2009	CO		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	ANTH	EMERGENT BIOSOLUTIONS	FAV171	4	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Patient did not know she was pregnant at the time of vaccination and was vaccinated with Anthrax and HPV

Other Meds: No other medications

Lab Data: HCG positive

History: No medical problems

Prex Illness: No illness at the time - no illness

Prex Vax Illns:

Vaers Id: 348801-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Dec-2008	01-Dec-2008	0	09-Jun-2009	10-Jun-2009	FL		01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0545X	2	Unknown	Intramuscular	HPV4 MNQ

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Anorexia, Arthralgia, Body temperature increased, Condition aggravated, Fatigue, Headache, Lyme disease, Malaise, Migraine, Muscular weakness, Myalgia, Nausea, Pain in extremity, Pelvic inflammatory disease, Pyrexia, Vaccine positive rechallenge

Symptom Text: Beginning with 2nd gardasil vaccination, been having myriad of symptoms. Initial symptoms included headaches that started after the first vaccination and worsened after 2nd vaccination. Treated by family physician/P.A. for migraines on several occasions. After 3rd and final vaccination, symptoms included worsening headache, severe joint pain, muscle aches, intermittent low grade fever, malaise, severe fatigue, muscle weakness, etc. 6/26/09 Received ER medical records of 1/11/2009. FINAL DX: abdominal pain, PID; myalgias; Lyme disease. Records reveal patient experienced RLQ abdominal pain, nausea & anorexia x 1 day. Had started period that day. Temp in ER 99.3. D/c to home. Seen in ER again on 2/11/09. Had been dx w/Lyme disease wk prior & had pain in legs & arms, diffuse myalgias. Being tx w/oral antibiotics. Referred to Rheum.

Other Meds: Ortho Tri-Cyclene Low, Midrin

Lab Data: ** Date indicated in date of vaccination is 3rd and final dose of gardasil vaccination when existing symptoms severely worsened. 6/26/09 Received medical records LABS: CT abd WNL.

History: Seasonal allergies only 6/26/09 Received medical records PMH: OCP. orthopedic surgery.

Prex Illness: none

Prex Vax Illns: none~ ()~~0~Patient|none~ ()~~0~Sibling

Vaers Id: **348802-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	09-Jun-2009	09-Jun-2009	0	09-Jun-2009	10-Jun-2009	MN		10-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF456BA	6	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: The client's sister also received an immunization and was discussing other shots she'd received in the armed forces. Client stated she felt dizzy. I had her sit for several minutes. She said she felt better and walked to the waiting room where she began to faint. We lowered her to the floor. We sat with her for several more minutes and gave her some cold water. She said she hadn't eaten any lunch and hadn't had much liquid today. I walked with her to the front door after she stated she felt much better. Her sister was to drive her home. She said she would eat something when she got home.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **348807-1** **Related reports:** 348807-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Apr-2009	24-Apr-2009	1	09-Jun-2009	10-Jun-2009	TX		06-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1423X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Allodynia, Back pain, Balance disorder, Blood immunoglobulin G, Blood immunoglobulin M, Chest pain, Dizziness, Dysphoria, Dyspnoea, Fatigue, Flat affect, Headache, Heart rate increased, Lymphadenopathy, Muscular weakness, Musculoskeletal discomfort, Nausea, Neck pain, Neuralgia, Neurological examination abnormal, Neuropathy peripheral, Pain in extremity, Pallor, Paraesthesia, Skin burning sensation, Vaccination complication

Symptom Text: Gardasil #1 (1423X) given in right arm on 4/23/09. Adverse reactions symptoms began 4/24/09 exhibited by: dizziness, headache, stomach pain, nausea, chest pains, shortness of breath, pins/needle sensations to feet, burning of skin, nerve pain to right elbow, fatigue, muscle weakness to legs, nausea, swollen lymph nodes to neck. Physician contacted 4/28/09 because this was felt to be in direct relation to the vaccine. She felt it was viral. 6/03/09 Same physician seen due to symptoms becoming more severe. Lab work drawn to rule out Mono due to swollen lymph nodes. 6/08/09 Pediatric Neurologist seen who confirmed that the symptoms were directly related to the Gardasil injection. Diagnosed peripheral neuropathy. 6/17/09 Medical and immunization records received DOS 4/23/09 to 6/3/09. Assessment: Pain & tingling, fatigue, lymphadenopathy. Patient presented with fatigue, headache, dizzy, chest pain, tingly feeling in arms and legs, pale, tender cervical lymph nodes. Referral to neurologist. LABS and DIAGNOSTICS: Planned CBC, ESR, CRP, Electrolytes, EBV, IgG, IgM 8/3/09 Consultant medical records received DOS 12/12/08 to 6/29/09. Assessment: New onset symptoms after Gardasil. Patient presents with dizziness and waves of nausea. Chest pain, shortness of breath, and intermittent bifrontal headaches. Tingling of feet and hands with associated pain. Burning sensation in hands and quadraceps muscles. Off balance. Back pain. EB Virus pending. Neuropathic type pain - ulnar region. Allodynic pain. Tender in C2 to C6. Heart rate 74 and standing heart rate 100. Flat affect and dysphoric mood.

Other Meds: Lexapro

Lab Data: CBC with diff/ plt, C-reactive protein, SED rate, electrolyte panel, Epstein Barr AB panel 6/17/09 Medical and immunization records received DOS 4/23/09 to 6/3/09. LABS and DIAGNOSTICS: Planned CBC, ESR, CRP, Electrolytes, EBV, IgG, IgM.

History: OCD. 6/17/09 Medical and immunization records received DOS 4/23/09 to 6/3/09. OCD, depression, anxiety, suicide attempts. Kidney stones. Weakness, dizziness. Allergy - Lamictal. 8/3/09 Consultant medical records received DOS 12/12/08 to 6/29/09. Tremor with intention, obsessive-compulsive dysfunction, mood disturbance. Allergy to Lacmictal. Kidney stone. Flexion of torso occuring m

Prex Illness: Healthy

Prex Vax Illns:

Vaers Id: **348807-2** **Related reports:** 348807-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Apr-2009	23-Apr-2009	0	10-Jul-2009	22-Jul-2009	--		29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1423X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Back pain, Chest pain, Dizziness, Fatigue, Headache, Hypoaesthesia, Muscle spasms, Muscular weakness, Nausea, Neuralgia, Neuropathy peripheral, Paraesthesia, Presyncope, Thirst, Visual impairment

Symptom Text: She received the first GARDASIL injection on 4/23/2009. Symptoms began developing on 4/24/2009. Initially, she was only dizzy and nauseous. As time progressed she has become sicker. She began having headaches, back pain, chest pain, abdominal pain, muscle weakness, numbness and tingling to feet, nerve pain, near fainting, visual disturbances, back pain, muscle cramps, constant thirst, chronic fatigue. She has been diagnosed with peripheral neuropathy. There are over 15,000 VAERS reports regarding this vaccine and that is only current since April 30. And that number is not accurate. There are many, many more that have not made the connection of their illness being caused by the GARDASIL. How many girls need to be injured and killed by this vaccine before the FDA pulls it from the market? This is the organization that we depend upon to protect us - you have completely failed my once healthy daughter! She is now "one less" healthy teenager!

Other Meds:

Lab Data: CBC, SED rate, Epstein Barre, electrolyte, c-reactive protein 6/03/09 Vit B. 12 level, Folic acid CXR, EKG 6/16/09 CBC w/differential, T3, T4, Vit. D 6/16/09

History: Allergic to LAMICTAL given for OCD symptoms

Prex Illness:

Prex Vax Illns:

Vaers Id: **348830-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Feb-2009	13-Feb-2009	0	10-Jun-2009	11-Jun-2009	FR	WAES0903USA00342	11-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1202U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a health care professional concerning a 16 year old female who on 19-DEC-2008 was vaccinated with the first dose of GARDASIL. On 13-FEB-2009, the patient was vaccinated with the second dose of GARDASIL. Concomitant therapy included MICROGYNON 30. The patient was pregnant at time of the GARDASIL injection (gestation week unknown at time of reporting): date of last menstruational period was in January 2009. Pregnancy testing has been performed by reporter on 13-FEB-2009. Pregnancy testing has been performed by reporter on 13-FEB-2009. No adverse event reported. Follow-up information from a health care professional indicated that the patient (reference: TMI-2009-95) received the first dose of GARDASIL on 19-NOV-2008, not on 19-DEC-2008 as was previously reported. The second dose of GARDASIL was from lot #1202U, batch #NJ31210. Concomitant treatment included MICROGYNON 30 since August 2008. At the administration of the second dose of GARDASIL, gestation period was estimated at +/- 7 weeks. The date of birth was foreseen in October 2009. Follow up information received from a health care professional on 11-MAR-2009: Voluntary termination of pregnancy on 03-MAR-2009. Upon internal review, voluntary termination of pregnancy was determined to be an other medical event. Additional information has been requested. Other business partner numbers include E2009-01434.

Other Meds: MICROGYNON 30, Aug08 - Unk

Lab Data: beta-human chorionic gonadotropin (unsp), 13Feb09

History:

Prex Illness: Pregnancy NOS (LMP = 01Jan09)

Prex Vax Illns:

Vaers Id: **348831-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Mar-2009	08-Apr-2009	8	10-Jun-2009	11-Jun-2009	FR	WAES0906USA00969	11-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0779X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Arthralgia, Asthenia, Muscular weakness, Myalgia, Pain, Vomiting

Symptom Text: Information has been received from a physician concerning a 12 year old female patient with no relevant medical history reported, who received the first dose of GARDASIL (lot number 0779X, batch number NJ32820) via intramuscular route on 31-MAR-2009. Eight days after vaccination, on 08-APR-2009, the patient experienced vomiting. On 27-APR-2009, i.e. 27 days after vaccination, she also developed myalgia, arthralgia and lower member myasthenia. She was also found to have bilateral pain. She had been given anti-emetic therapy with PRIMPERAN and metoclopramide but with no effect. The only medication the patient was taking at the moment was omeprazole. She was on a liquid diet, because of her symptoms. Furthermore, at the end of each day, she presented with a loss of strength. She was not attending classes because of her symptoms. On 16-MAY-2009, she presented with behaviour changes which resolved on 17-MAY-2009. Abdominal and muscular ultrasounds, blood analysis and medical examination were performed. The reporter considered that everything was normal except a possible conversion disorder diagnosis written in the emergency room report, but the reporter disagreed with this possible diagnosis. To be noted that a slight creatinine decreased (0.4 for a minimum 0.5 threshold) in a blood exam on 09-MAY-2009, was not highlighted by the reporter, considering that all the other results were normal. It was noteworthy that the events were reported as serious due to the duration of the events, except for behaviour changes which were reported as non serious as it was a "one-time situation". At the time of reporting, the patient was still vomiting and had not yet recovered from the other events either. The reporter considered myalgia, arthralgia, pain, myasthenia and strength to be other important medical events. Other business partner numbers included: E2009-04670. Additional information has been requested.

Other Meds: metoclopramide

Lab Data: ultrasound, abdominal and muscular: Normal; diagnostic laboratory test, blood analysis: Normal; serum creatinine, 09May09, 0.4, minimum 0.5 threshold

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **348842-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Mar-2009	12-Mar-2009	0	10-Jun-2009	11-Jun-2009	FR	WAES0906USA00763	11-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Dizziness, Nausea, Vomiting

Symptom Text: Initial information has been received from a health authority (HA ref. DK-DKMA-20091250). It was reported that a 16 year old female patient who on 12-MAR-2009 was vaccinated with the first dose of GARDASIL IM left arm (batch # NJ50800, lot # 0773X). On the same day the patient experienced dizziness, nausea and vomiting a few times. Dizziness was initially interpreted as vestibularisneuritis by an ear-nose-throat specialist (date not reported). MR-scan was ordered (result not reported). At the time of report the patient had not recovered. Other business partner numbers include: E2009-04644. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **348843-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Feb-2008	01-Aug-2008	177	10-Jun-2009	11-Jun-2009	FR	WAES0906USA00947	01-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Acute tonsillitis, Familial risk factor, General physical health deterioration, Ketoacidosis, Polydipsia, Polyuria, Rash pruritic, Somnolence, Type 1 diabetes mellitus, Urticaria, Weight decreased

Symptom Text: Information has been received from a gynecologist that a 14 year old female patient who was vaccinated IM with a first dose of GARDASIL (lot number and injection site not reported) on 06-FEB-2008. On unspecified date ("in a temporal relationship to GARDASIL vaccination"), the patient developed diabetes mellitus type I. The patient had not recovered at the time of reporting. Upon internal review on 04-JUN-2009, the case was considered medically significant. Type I diabetes mellitus was considered to be disabling by the gynecologist. Other business partner numbers included (E2009-04463). No further information is available. Follow up has been received on 16-JUN-2009. The hospital report was provided. The patient was hospitalized from 26-AUG-2008 until 12-SEP-2008. Hospital diagnosis: "Manifestation of diabetes mellitus type I with ketoacidosis and precoma diabeticum". Since a "few weeks before hospitalization" the patient experienced polydipsia and polyuria and lost 7 kg of weight. Since about 2 weeks before hospitalization her general condition began to reduce. Since one week she suffered from angina tonsillaris which was treated with antibiotics. Symptoms worsened remarkably and she was hospitalized on 26-AUG-2008. At the time the patient was slightly drowsy (Glasgow coma scale 14) showed Kussmaul respiration and signs of exsiccosis Hyperglycemia (27 mmol/L) had been determined by the physician on emergency. Therapy was started with rehydratation and insulin intravenous. Intensive insulin therapy (LANTUS and NOVORAPID) was started from the third day of hospitalization. In the course of the quantity of insulin could be measurably reduced. In the meantime the patient developed a pruritic, partly urticarial rash which was successfully treated with FENYSTIL. Lab findings see lab comments: Gliadin-IgA and Gliadin-IgG, tTG(endomysium) Ig A were normal. The patient had a family Medical history of Diabetes mellitus type 2 (maternal grand father). The patient was discharged in a good general condition. Duration and outc

Other Meds: Unknown

Lab Data: Unknown; diagnostic laboratory test, 26Aug08, 26.1, Diabetic acidosis ABB; arterial blood pCO(2), 26Aug08, 16.7; arterial blood pH, 26Aug08, 7.04; plasma HCO(3), 26Aug08, 44.8; serum blood urea, 26Aug08, 6.7; serum creatinine, 26Aug08, 117;

History: None; Family history of diabetes

Prex Illness:

Prex Vax Illns:

Vaers Id: **348844-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-May-2009	20-May-2009	0	10-Jun-2009	11-Jun-2009	FR	WAES0906MYS00003	11-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Blood test, Dizziness, Epilepsy, Nausea, Syncope, Urinary incontinence

Symptom Text: Information has been received from a physician concerning a 22 year old female who on 20-MAY-2009 was vaccinated with the first dose of GARDASIL, 0.5 mL, intramuscular. On 20-MAY-2009, few seconds after vaccination, patient complained of giddiness, felt like vomiting and fainted for few seconds. Doctor commented the patient was having epileptic experience as the patient cannot control urination and did not remember anything after regaining consciousness. Patient was put on IV drip after regaining consciousness and was sent to hospital for further checkup & blood test. Patient was not hospitalized. Patient does not suffer from hypoglycemic condition. Subsequently, the patient recovered from epilepsy and fainting episode. Causality is unknown. Upon internal review, epileptic experience was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **348845-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Feb-2009	25-Feb-2009	1	10-Jun-2009	12-Jun-2009	FR		12-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0858X	2	Left arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Juvenile arthritis, Pain in extremity

Symptom Text: Hands and feet hurt next morning. Started taking ADVIL, NAPROXEN with days. Within 4 weeks, full-on J/A, polyarticular. Seen at hospital. Now on PREDNISONE and METHOTREXATE.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348852-1** **Related reports:** 348852-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Jun-2009	08-Jun-2009	0	10-Jun-2009	11-Jun-2009	DE		11-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Gluteous maxima	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Presyncope, Syncope

Symptom Text: Patient had severe vaso response and fainted at check out window approximately 8 minutes after receiving vaccine. She fell hard and hit the floor with her head. An ambulance was called due to the magnitude that she hit her head and it took her quite a long time (roughly 10 minutes) to completely come to and know her surroundings. She had a very large knot on her forehead/temple area and we felt the need for the ER to evaluate the head for any trauma associated with the fall.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348852-2** **Related reports:** 348852-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Jun-2009	08-Jun-2009	0	17-Jul-2009	19-Aug-2009	DE	WAES0906USA01710	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness, Presyncope

Symptom Text: Information has been received from a physician concerning a 25 year old female patient with no pertinent medical history or no known drug allergies, who on 08-JUN-2009 was vaccinated with the first dose of GARDASIL (Lot: 661846/1312X) intramuscularly. Concomitant therapy included hormonal contraceptives (unspecified). After vaccination, while checking out she had a "vasovagal response" and passed out. The patient was observed in the office prior to checking out. The patient hit her head in the fall. She was sent to the emergency room for evaluation and was discharged home. The office was going to contact her for follow up. At the time of reporting the patient's status was unknown. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348870-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Apr-2009	23-Apr-2009	2	10-Jun-2009	12-Jun-2009	TX		27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Dizziness, Fall, Rash, Rash pruritic, Syncope, Urticaria, Visual impairment

Symptom Text: Rash beginning on bilateral arms. On and off x 1 wk. Rash down bilateral legs and cont. on arms x 3-4 days. Began with rash to face and neck 6-8-09 comes and goes. Rash seized yesterday began again today. 7/24/09 ER records received DOS 6/3/09 and 6/22/09. Assessment: Hives/Urticaria. Hypokalemia, bulemia. Patient presents on 6/3/09 with an itchy urticarial rash on arms, legs and trunk, of one month duration. On 6/22/09 c/o syncope X2, feels weak, falling. Lightheadedness, trouble with vision. Collapsed.

Other Meds: None

Lab Data: Immunocap. 7/24/09 ER records received DOS 6/3/09 and 6/22/09. LABS and DIAGNOSTICS: CHEM - Postassium 2.7 mmol/L (L). CBC - MCH 31.5 PG (H). Urinalysis - pH 9.0 (H), Protein trace, Bacteria 3+, Mucous trace, Amorph Phos 2+.

History: 7/24/09 ER records received DOS 6/3/09 and 6/22/09. Chicken pox. Bulemia, depression.

Prex Illness:

Prex Vax Illns:

Vaers Id: **348873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Dec-2008	14-Jan-2009	27	10-Jun-2009	11-Jun-2009	CA	CA090005	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Anxiety, Arthralgia, Back pain, Chiropractic, Depressed mood, Foot deformity, Gait disturbance, Joint swelling, Joint warmth, Juvenile arthritis, Lymphadenopathy, Musculoskeletal pain, Myopia, Oedema peripheral, Pain in extremity, Physiotherapy, Pruritus, Rash, Screaming, Wheelchair user

Symptom Text: Diagnose Juvenile Rheumatoid Arthritis-> seen at medical center. Tx Prednisone, Methotrexate, LEUCOVORIN. 1/09 started having back pain, unilateral shoulder, arm pain, followed by progressive knee pain and swelling, limitation of activity. 8/4/09 Rheumatology consult records received DOS 3/5/09 to 5/15/09. Assessment: Polyarticular Juvenile Rheumatoid Arthritis. Patient presented with pain in back, knees, shoulders, ankles, feet, elbows and wrists. Pain started in back and then started involving other joints. Difficulty with range of motion and activities in school. Involves 1 or 2 joints for 2-3 joints then moves on to a different joint. She has noticed swelling in knees and hands. Recent URI, fever, chills, sore throat, and cough. Posterior pharynx has erythema with mucus. Wamth of elbows with synovial boggy tissue. Swollen MCP joints. Right hip decreased ROM and pain. Warm both ankles. Synovitis PIP joints. Swelling of knees. Slight scoliosis. Pes planus. Later refusing to walk. Screams when leg or foot touched. Difficulty with ADLs. Chiropractic treatment. Physical therapy. Nearsighted. Rash on arms. Itchy rash on foot. Anxious, depressed affect. Cervical lymphadenopathy. Uses wheelchair.

Other Meds: None

Lab Data: Elevated ANA; Elevated Rheumatoid Factor. 8/4/09 Rheumatology consult records received DOS 3/5/09 to 5/15/09. LABS and DIAGNOSTICS: CBC - WBC 15.26 K/uL (H) RDW-CV15.3% (H) Seg 77% (H) Lymph 21% (L) Polychromasia (slight) Target Cell (few

History: None. 8/4/09 Rheumatology consult records received DOS 3/5/09 to 5/15/09. Hives - back and face. Allergic to dogs, cats, walnuts, oak tree and pollen. Claritin for hives. Nosebleeds from Nasonex. Oral ulcer. Sinus problems, headaches, double vision. Parotitis. Tonsillectomy. Toe fracture.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348877-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	10-Jun-2009	10-Jun-2009	0	10-Jun-2009	11-Jun-2009	WA		11-Jun-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB286AA	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3039AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2827CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: About 5 mins after rec'vg all imm. appeared fine; started to stand then fainted x 20-30 secs. Revived w/cool water compress & light stimulation. Remained lying then sitting x 15 more minutes then home w/mom. Sustained no injury.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **348908-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Apr-2009	Unknown		11-Jun-2009	11-Jun-2009	AR		31-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB262BA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	0381X	0	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	U2689AA	0	Unknown	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B02UEA	0	Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	1784X	1	Unknown	Subcutaneously	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB847BA	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None stated

Other Meds:

Lab Data: Unknown

History: She is pregnant

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **348918-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	29-May-2009	29-May-2009	0	11-Jun-2009	12-Jun-2009	TX	WAES0906USA00544	12-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Pain in jaw, Paraesthesia oral, Sensation of foreign body, Tremor

Symptom Text: Information has been received from a nurse concerning a 23 year old female who on 29-MAY-2009 was vaccinated with the first dose of GARDASIL, 0.5ml/IM. After about 20 minutes the patient experienced the feeling of a lump in her throat, tingling of her tongue, achy joints and body tremors. Follow up information has been received from a physician reporting that when the patient had gone to the emergency room she was given I.V. BENADRYL and Benztropine mesylate (MSD) and released. The physician stated that he received a call from the patient a few minutes ago and the patient said that she was starting to have body tremors again as well as aching of her jaw. At the report time the patient was on her way to see the physician and the outcome was unknown. Upon internal review tingling of her tongue, body tremors and lump in her throat were considered as Other Important Medical Events. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **348919-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	12-Feb-2008	12-Feb-2008	0	11-Jun-2009	12-Jun-2009	IL	WAES0802USA05190	12-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arrested labour, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer, for the Pregnancy Registry for GARDASIL concerning herself, a 26 year old female, who on 12-FEB-2008 was vaccinated with her first dose of GARDASIL (lot# not reported). Concomitant therapy included Zoloft. On 18-FEB-2008 the patient found out she was about 6 weeks pregnant. Her LMP was estimated to be 06-JAN-2008 with a due date of 12-OCT-2008. The patient had a positive home pregnancy test. Her outcome was not reported. Follow up information was received from the consumer and the office nurse, for GARDASIL, Pregnancy Registry product. The office nurse reported that they did not even know the patient was pregnant. The patient reported that she went into spontaneous labor, but her labor didn't progress fully, and she had a cesarean section. On 22-OCT-2008, the patient delivered a health baby boy (8 pounds, 13 ounces) with no problems. At the time of reporting, the patient recovered completely from the C-section, and had no complications. Upon internal review, cesarean section due to labor not progress fully was determined to be an other important medical event. Additional information is not expected.

Other Meds: ZOLOFT

Lab Data: Beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/6/2008)

Prex Vax Illns:

Vaers Id: 348920-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-May-2009	28-May-2009	10	11-Jun-2009	12-Jun-2009	FL	WAES0906USA01158	23-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Antinuclear antibody, Biopsy bone marrow, Blood product transfusion, Complement factor C3, Complement factor C4, Full blood count, Idiopathic thrombocytopenic purpura, Metabolic function test

Symptom Text: Information has been received from a physician concerning a 16-year-old female patient with no medical history who was vaccinated with the second dose of GARDASIL. Concomitant therapy included Depo-Provera. A week or two after the second dose of GARDASIL the patient developed idiopathic thrombocytopenic purpura and was admitted to hospital and given intravenous immune globulin (IVIG) 2 doses. The following lab diagnostics studies was performed: Complete blood count, Comprehensive Metabolic Panel, Antinuclear Antibody Test, serum complement C3/C4 ratio, Immunoglobulin A, Bone marrow biopsy. The patient has been discharged. The patient's idiopathic thrombocytopenic purpura was considered to be disabling and an other important medical event. The patient had not been recovered. Additional information has been requested. 6/22/09-records received for DOS 5/28-5/30/09- DC DX: ITP status post 2 doses of IVIG with slight improvement of platelet count. Presented with newly diagnosed ITP with mild bruising. ICD-9 287.31.

Other Meds: DEPO-PROVERA

Lab Data: Unknown 6/22/09-records received-Two weeks prior platelet count of 26. Rheumatology labs negative.

History: None 6/22/09-records received- PMH Depo Provera.

Prex Illness:

Prex Vax Illns:

Vaers Id: **348921-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	29-May-2009	29-May-2009	0	11-Jun-2009	12-Jun-2009	FR	WAES0906MEX00002	12-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Tonic clonic movements

Symptom Text: Information has been received from a physician concerning a 9 year old female with convulsion (tonic-clonic convulsions since 6 years before the report, last episode 4 years before of this report) who on 29-MAY-2009 was vaccinated with GARDASIL. Concomitant therapy included valproate magnesium. On 29-MAY-2009 the patient experienced seizure after the first dose of GARDASIL was administered. The convulsion was characterized by tonic-clonic movements with 5-10 seconds to duration, without sphincter relaxation. The patient recovered from seizure on 29-MAY-2009 without additional treatment. The reporter felt that seizure was related to therapy with GARDASIL. Upon internal review seizure was considered as other important medical event. Additional information has been requested.

Other Meds: valproate magnesium

Lab Data: None

History:

Prex Illness: Convulsion

Prex Vax Illns:

Vaers Id: **348922-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	22-Apr-2009	22-Apr-2009	0	11-Jun-2009	12-Jun-2009	FR	WAES0906MEX00003	12-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a physician concerning a 10 year old female who on 22-APR-2009 was vaccinated with GARDASIL. There was no concomitant medication. On 22-APR-2009 after the GARDASIL administration the patient experienced seizure characterized by tonic movements (duration not reported), and faint (3 episodes, duration of each episode not reported). On 22-APR-2009 the patient recovered from seizure and faint without medical treatment. The reporter felt that seizure and faint (3 episodes) were related to therapy with GARDASIL. Upon internal review seizure was considered as other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **348923-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-May-2009	16-May-2009	3	11-Jun-2009	12-Jun-2009	FR	WAES0906USA00748	12-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0779X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Purpura, Pyrexia, Urticaria

Symptom Text: Information has been received from the Health Authorities on 29-MAY-2009 under reference number N200905557 concerning a 12 year old female with no other relevant history who on 13-MAY-2009 was vaccinated with the first dose of GARDASIL (batch# NJ32820, lot# 0779X, intramuscular administration). On 16-MAY-2009 the patient experienced generalized purpura, urticaria and fever. She was given desloratadine, but without effect, and paracetamol as corrective treatment. Previous adverse reactions to any drug were unknown. The patient recovered from fever within 2 days, and was on her way to recover from purpura and urticaria. Purpura and urticaria were considered medically significant. Other business partner number included: E200904634. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348924-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-May-2009	01-May-2009	0	11-Jun-2009	12-Jun-2009	FR	WAES0906PHL00008	12-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Muscle twitching

Symptom Text: Information has been received from a physician concerning a 17 year old female daughter of a colleague who is a visiting physician in the same hospital who in May 2009, was vaccinated with GARDASIL. In May 2009, the patient experienced seizure and muscle twitching. Upon internal medical review, seizure was considered an other important medical event. No further information is available. The contact details of the primary reporter has not yet been obtained. Information will be added if and when the physician's contact number has been acquired.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348929-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-May-2009	29-May-2009	0	11-Jun-2009	11-Jun-2009	NC		11-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Generalized Urticaria Patient treated with Prednisone

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348964-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Apr-2009	06-Apr-2009	0	11-Jun-2009	15-Jun-2009	FL		15-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1379U	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2866AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1312X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Pallor

Symptom Text: Immediately after vaccine was given, the patient developed pallor and was dizzy.

Other Meds:

Lab Data:

History:

Prex Illness: none known

Prex Vax Illns:

Vaers Id: **348965-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-May-2009	29-May-2009	0	11-Jun-2009	15-Jun-2009	PR	PR0910	15-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	01004	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Anorexia, Dizziness, Headache, Nausea, Somnolence, Speech disorder

Symptom Text: HEADACHE, DIZZINESS, PROBLEMS WITH SPEECH, NAUSEA, STOMACH ACHE, SLEEPINESS, NO APPETITE. 6/12/09 Medical records received DOS 9/14/2006 to 6/4/09. Medical progress notes are illegible.

Other Meds:

Lab Data: CBC, TSH 6/12/09 Medical records received DOS 9/14/2006 to 6/4/09. LABS and DIAGNOSTICS: Thyroid Function Tests all WNL. CBC - WBC 10.1 10^3/uL (H) NE 44.5% (L) LY 45.7% (H) MO 8.7% (H) EO 0.6% (L) BA 0.3% (L) NE 4.6 10^3/uL (L) LY 4.6

History: NO

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **348974-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-May-2009	29-May-2009	0	11-Jun-2009	15-Jun-2009	CA		15-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Contusion, Gaze palsy, Grand mal convulsion, Head injury, Headache, Loss of consciousness, Muscle twitching, Neck pain, Pallor

Symptom Text: April 2009: Pt. had conjunctivitis in both eyes and was tx'd with antibiotic gtts x5 days. 8 May 09: Annual physical exam was normal. Conjunctivitis had cleared. Gardasil vaccine was offered, but patient and parent refused. 26 May 09: Eye discharge (OU) in a.m., so made MD appt. 29 May 09: Went to physician to have eyes checked again for conjunctivitis return. MD noticed that Gardasil had not been given at the 8 May 09 annual physical exam. MD stated that pt. really should have the Gardasil vaccine because "it will save your life." Pt. finally consented. At 9 a.m., Gardasil was administered in the left deltoid. Pt. and mother immediately went to front desk to schedule next appt. to receive Gardasil (2nd in a series of 3 Gardasil vaccinations). At 9:10 am, at the front desk, the nurse who had given the vaccine came out to offer ibuprofen for deltoid pain. The pt. was pale and tried to hold onto the counter when she lost consciousness. She hit the back of her head on the floor and sustained a contusion. The pt's mother, the RN and the MD came to the pt's side. The pt. was unconscious for about 5 minutes. During the 5 minutes of unconsciousness, she sustained clonic/tonic seizures with her hands clutching up and down. Her eyes rolled up and to the right and she was "twitching." The RN rubbed knuckles on the pt's sternum to evaluate consciousness while an oxygen mask (100% oxygen) was applied. An EMT who happened to be in the waiting room assisted by holding the pt's head to keep it from banging against the floor repeatedly. After 5 minutes, the pt. spontaneously opened her eyes and was able to accurately say her name, the date and the location. She complained of neck and head pain. 911 was called and the pt. brought to the ER at 10:30 am. Pt. kept asking what had happened and had no recollection of any events after holding onto the reception desk in the waiting room. Neuro status was normal except for the head contusion. CV status was evaluated by ultrasound which was found to be normal (ER phy

Other Meds: last medication pt. had taken was on 24 May 09: 400 mg ibuprofen for menstrual cramps.

Lab Data: 29 May 09: cardiac ultrasound was normal. 29 May 09: CBC was normal.

History: None: Pt. has no history of seizures. She does have a history of seasonal allergies, but does not take any medication for it. Pt. had a history of allergic reaction to bee stings (swelling and pruritis at sting site) and poison oak (both successfully treated with Benedryl).

Prex Illness: conjunctivitis, otherwise the pt. was in completely normal state of good health.

Prex Vax Illns:

Vaers Id: **348976-1** **Related reports:** 348976-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Jun-2009	11-Jun-2009	0	11-Jun-2009	15-Jun-2009	AR		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Cerumen impaction, Concussion, Contusion, Convulsion, Dizziness, Dyskinesia, Erythema, Face injury, Facial pain, Headache, Incontinence, Injection site pain, Injury, Joint injury, Loss of consciousness, Mydriasis, Posturing, Presyncope, Pupils unequal

Symptom Text: Approx 90 seconds after the first injection my daughter became faint and passed out, she then began having a seizure, the entire episode lasted approx 2 minutes. After being treated and stabilized at the clinic, we saw our family DR approx one hour later. she had multiple xrays due to the injuries when she fainted, she has a mild concussion with slight dialation of the left pupil. she has a lingering headache, (we are sure this is at least in part due to the facial injuries from the fall to the tile floor). There is signigiant pain at the injection site which is being treated with ice packs and extra strenght Tylenol (no motrin allowed due to the high level of bruising) after seeing our family DR she has refered us to a Neurologist to rule out any underlying factors leading to the fainting and seizures that our daughter experienced today. 7/29/09 Consultant records received DOS 6/11/09. Assessment "faint" vasovagal Patient felt dizzy, passed out, loss of consciousness, posturing, incontinence, hit (R) face, (R) hip, (R) knee, some jerking. Presents with erythema (R) cheek / skin / (R) Hip and knee. Contusion (R) hip (R) knee (R) face. Face and knee feel sore. (L) pupil > (R) properly responding. Auditory canal blocked with wax.

Other Meds: NONE

Lab Data:

History: MILD SCOLIOSIS. 7/29/09 Consultant records received DOS 6/11/09. Similar episode Jan 08 - jerking, no loss of consciousness, seen in ER.

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **348976-2 (S)** **Related reports:** 348976-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Jun-2009	11-Jun-2009	0	16-Jun-2009	22-Jun-2009	--		23-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: My Daughter received the GARDASIL shot this morning, she fainted and had a seizure the episode lasted approx. 2 minutes. She is receiving medical care and under observation.

Other Meds:

Lab Data: She was advised by our family DR to discontinue the remaining GARDASIL shots until further testing can be done. She will be following up with a Neurologist to rule out any underlying factors that may have contributed to the episode. She und

History: No pre-x conditions. Healthy and athletic, plays sports year round.

Prex Illness:

Prex Vax Illns:

Vaers Id: **349002-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Jun-2009	08-Jun-2009	0	12-Jun-2009	15-Jun-2009	WI		25-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB42EB	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis

Symptom Text: After administration of GARDASIL patient got dizzy + started perspiring.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **349003-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Nov-2007	26-Nov-2007	0	12-Jun-2009	15-Jun-2009	MI	WAES0801USA05575	15-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aborted pregnancy, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a 15 year old female with no medical history and no drug allergies, who on 26-NOV-2007 was vaccinated intramuscularly in the left arm with a 0.5mL first dose of GARDASIL (Lot# 658563/1063U). On 28-JAN-2008 the patient was vaccinated with a second dose of GARDASIL (Lot# 658563/1063U). There was no concomitant medication. Subsequently, the patient was pregnant. The patient believed her last menstrual period to be 20-NOV-2007 and her estimated delivery date was 26-AUG-2008. The patient was seen in the office. A urine pregnancy test was taken. No symptoms were reported. At the time of the report, the outcome of the patient was unknown. No product quality complaint was involved. Follow up information was received from the physician who reported that the patient's EDD was 11-AUG-2008. On an unspecified date the patient aborted her pregnancy as it was unwanted pregnancy. Upon internal review, pregnancy aborted was considered to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: urine beta-human

History:

Prex Illness: Pregnancy NOS (LMP=11/20/2007

Prex Vax Illns:

Vaers Id: **349004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Jun-2008	06-Aug-2008	41	12-Jun-2009	15-Jun-2009	OH	WAES0901USA03065	15-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breech presentation, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 17 year old female patient with no known drug allergies who on 24-APR-2008 (also reported as 28-APR-2008) was vaccinated with the first 0.5 ml IM dose of GARDASIL. On 26-JUN-2008 the patient received the second 0.5 ml IM dose of GARDASIL. On 24-OCT-2008 the patient received the third 0.5 ml IM dose of GARDASIL (lot # 659439/1267U). Concomitant therapy included insulin and SYNTHROID. At the time of the third dose the patient reported she was pregnant and LMP was 06-OCT-2008. Lab diagnostics studies included ultrasound and bloodwork. Ultrasound showed that LMP was 06-AUG-2008. Estimated delivery date was 13-MAY-2009. Bloodwork for OB profile was performed with all results in normal limits. The patient sought unspecified medical attention. Follow up information has been received from a completed questionnaire by a physician. It was reported on the questionnaire that the patient with diabetes, hypothyroidism had no complication and no infections or illnesses during pregnancy. On 24-DEC-2008, 18-FEB-2009, 01-APR-2009, 15-APR-2009 and 29-APR-2009, the patient had ultrasounds which were normal. On 30-APR-2009 at 38 weeks from LMP, the patient underwent a cesarean section due to breech and had a normal female liveborn infant. There were no congenital anomalies. She was 9 lbs 2.2 oz weight, 21 inches long, apgar score was 9/9. Upon internal review, cesarean section due to breech was considered to be an other important medical event. Additional information is not expected.

Other Meds: INSULIN; SYNTHROID

Lab Data: ultrasound, LMP was 06-AUG-2008; diagnostic laboratory, OB profile: all results in normal limits; ultrasound, 12/24/08, normal; ultrasound, 02/18/09, normal; ultrasound, 04/01/2009, normal; ultrasound, 04/15/09, normal; ultrasound, 04/29/09

History:

Prex Illness: Pregnancy NOS (LMP = 8/6/2008); Diabetes; Hypothyroidism

Prex Vax Illns:

Vaers Id: **349005-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		12-Jun-2009	15-Jun-2009	OH	WAES0906USA01328	15-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Toxic shock syndrome

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who is a tampon user and who on an unknown date was vaccinated with the first dose of GARDASIL. Three days later, the patient experienced toxic shock syndrome and was admitted to the hospital. It was reported that the patient was menstruating and was using a tampon at that time. The physician stated that the patient survived but she spent one week in the hospital. The patient's final outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349022-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Jun-2009	12-Jun-2009	0	12-Jun-2009	16-Jun-2009	WI		17-Jun-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2735AA		Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	0652X		Unknown	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB258AA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Client fainted for a few seconds. I held her in chair until she came to and then we got her on the exam table and let her rest for about 15 minutes. She was fine then and left with her parents. Client also stated she had had nothing to eat yet, shot was given at 10:45am.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: fainting~HPV (Gardasil)~1~17~In Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349025-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	10-Jun-2009	11-Jun-2009	1	12-Jun-2009	16-Jun-2009	VA		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947 X	2	Left arm	Intramuscular	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB116AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Oedema peripheral

Symptom Text: Approximately 24 hrs after vaccination. Noted left arm swelling and c/o numbness from shoulder to wrist. After 48 hrs remains swollen but no erythema numbness improving from elbow to wrist. Normal ROM,no weakness. Will try ibuprofen for inflammation.

Other Meds: NONE

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349031-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Jun-2009	12-Jun-2009	1	12-Jun-2009	16-Jun-2009	OR	OR200928	04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2870AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site rash, Injection site swelling, Pain in extremity, Pruritus, Rash, Skin warm, Urticaria

Symptom Text: Reports rash and swelling noted in left deltoid. Received 2 vaccines on 06/11/09, noticed soreness in Left arm 14 hours later. Awakened next morning ~ 26 hours later without problems until after showering. Pt states then noticed itching and rash on left arm with soreneess at the site of one of the injections. Observed by this writer~ 27 hours urticarial rash noted around one injection site~ 7x4 cm . Skin warm to touch and client afebrile (T- oral 98.4 F. To RTC on Monday with medical provider for followup.

Other Meds: OrthoTricyclen

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 349081-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	03-Nov-2008	03-Nov-2008	0	15-Jun-2009	16-Jun-2009	FR	WAES0902USA04681	16-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Threatened labour

Symptom Text: Information has been received from a healthcare professional, for GARDASIL, a Pregnancy Registry product, concerning a 20-year-old female patient with medical history of genital warts who received the second dose of GARDASIL (lot# not provided, batch # not provided) on 03-NOV-2008 while she was pregnant. Her last menstrual period was on 26-OCT-2008 and pregnancy was confirmed with U/S scan. At time of reporting the patient had no adverse effect. She had no concomitant treatment. Follow-up information received from the reporting physician on 04-JUN-2009 and transmitted by the distributor: Case upgraded to serious considering the following information: the 22 year old patient (corrected 05-JUN-2009) was hospitalized on 01-JUN-2009 due to a risk of premature labour. The patient was currently in her 31st week of gestation. The patient had received the second dose of GARDASIL via intramuscular route. At the time of reporting, the outcome was not reported. Threatened premature labour was considered an other important medical event. Other business partner numbers include: E2009-01324. No further information is available.

Other Meds: None

Lab Data: ultrasound, pregnancy confirmed

History: Genital wart

Prex Illness:

Prex Vax Illns:

Vaers Id: 349082-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	31-Dec-2007	01-Jun-2008	153	15-Jun-2009	16-Jun-2009	TX	WAES0806USA00890	16-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for the Pregnancy Registry for GARDASIL regarding an 18 year old female with depression and a history of attention deficit disorder (1988) who on 31-OCT-2007 was vaccinated intramuscularly with her first dose of GARDASIL (Lot # 657006/0188U; site not reported). On 31-DEC-2007, the patient was vaccinated intramuscularly with her second dose of GARDASIL (Lot # 658554/0928U; site not reported). On 31-MAY-2008 (also reported as 4 days ago), the patient took a home pregnancy test which was negative. On 03-JUN-2008, the patient was vaccinated intramuscularly with her third dose of GARDASIL (Lot # reported as "0178U"; site not reported). Concomitant therapy included an unspecified antidepressant. On 03-JUN-2008, the patient took four home pregnancy tests which were all positive. The LMP date was not reported. The patient sought unspecified medical attention in the office. The patient outcome was not reported. No additional information was provided. All telephone attempts to contact the physician have been unsuccessful. Follow up information was received from the licensed practical nurse concerning the 18 year old patient who experienced miscarriage in approximately June 2008 which was about 2-3 weeks after the initial report was called in June 2008. The patient was doing fine. Upon internal review, miscarriage was determined to be an other important medical event. Additional information is not expected.

Other Meds: [Therapy unspecified]

Lab Data: Urine beta-human, 05/31/08, negative; Urine beta-human, 06/03/08, positive

History: Attention deficit disorder

Prex Illness: Pregnancy NOS (LMP = Unknown); Depression

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349084-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	13-Jun-2008	Unknown		15-Jun-2009	16-Jun-2009	MD	WAES0806USA08747	16-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning an 18 year old female who on 13-JUN-2008 was vaccinated with the first dose of GARDASIL (lot # 658222/0927U). Subsequently the patient had a positive pregnancy test. The patient's LMP was not reported. Patient outcome was not reported. The patient sought unspecified medical attention by contacting the office. Follow-up information has been received from a physician who reported that the patient had an abortion. The abortion was not due to congenital anomaly or abnormal sonogram result. Patient decided on her own that she had too many unplanned pregnancies. Upon internal review, abortion was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **349086-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jul-2007	24-May-2008	328	15-Jun-2009	16-Jun-2009	DE	WAES0805USA05079	16-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Pregnancy induced hypertension

Symptom Text: Information has been received from a nurse, for the pregnancy registry for GARDASIL, concerning a female with no known allergies and no pertinent medical history who in approximately July 2007, was vaccinated IM with a dose of GARDASIL (lot#, and site not reported) 0.5 ml. There was no concomitant medication. The patient sought unspecified medical attention. The nurse reported that the patient is pregnant and "she's probably in labor now" but was not positive. The LMP (last menstrual period) and estimated date of delivery were not reported. Method of pregnancy confirmation was also not reported. The nurse did not have the patient's chart in front of her, so exact details could not be provided. Follow up information was received, for GARDASIL, a Pregnancy Registry product, which reported that the patient delivered a baby via C-section on 24-MAY-2008. The reporter said that the patient had mild pregnancy-induced hypertension (PIH), but she was not sure why the C-section was performed. The baby just turned one and was normal and healthy with no congenital anomalies. The patient worked in the office and everything turned out fine. Upon internal review, C-section was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **349088-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		15-Jun-2009	16-Jun-2009	--	WAES0906USA01783	16-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Headache, Intracranial pressure increased, Lymphadenectomy, Lymphadenopathy, Thyroid disorder

Symptom Text: Information has been received from a consumer concerning his 15 year old daughter who was vaccinated with GARDASIL. After the patient received the first dose of GARDASIL the patient had a headache. The patient was hospitalized after the second dose of GARDASIL with a lymphadectomy, lymphadenopathy of the neck and the heart, a thyroid lesion, intracranial hypertension and was hospitalized. The patient was 17 years old at the time of reporting. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349089-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Apr-2009	01-May-2009	2	15-Jun-2009	16-Jun-2009	FR	WAES0906USA00765	16-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	WH55600	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Appendicectomy, Appendicitis, Vomiting

Symptom Text: Information has been received from a foreign Health Authority on 28-MAY-2009 under reference number 200901985 concerning a 14 year old female adolescent, 55kg, who on 29-APR-2009 was vaccinated with the second dose of GARDASIL (intramuscular administration, batch# and site of administration not reported). 48 hours later the patient presented abdominal pain and vomiting. On 02-MAY-2009 the clinic data was compatible with appendicitis. The patient was hospitalized on 02-MAY-2009. On 03-MAY-2009 the patient had appendectomy (macroscopic analysis). The patient recovered. Other business partner number included: E200904508. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349109-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	10-Jun-2009	11-Jun-2009	1	16-Jun-2009	18-Jun-2009	CA		11-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0162Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3246BA		Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Complex partial seizures, Condition aggravated, Grand mal convulsion, Impaired driving ability, Neurological examination abnormal, Postictal state, Stereotypy, Tongue biting

Symptom Text: DURING A ROUTINE PHYSICAL, I WAS GIVEN A TETANUS AND GARDASIL VACCINE SHOT. APPROXIMATELY FIFTEEN AND A HALF HOURS AFTER THE FIRST INOCULATION OF THE VACCINE GARDASIL, I EXPERIENCED TWO ONSET GRAN MAL SEIZURES. SEIZURES OCCURED IN THE MORNING, WITHIN FOUR AND A HALF HOURS OF EACH OTHER. I WAS TRANSPORTED BY AMBULANCE AFTER BOTH EPISODES. AFTER FIRST SEIZURE, I WAS GIVEN A CT SCAN AND BLOOD WORK-UP. BOTH TESTS CAME BACK NEGATIVE. NO PRESCRIPTIONS WERE GIVEN. I WAS RELEASED FROM THE ER WITH INSTRUCTIONS TO FOLLOW UP WITH A NEUROLOGIST ASAP. AN HOUR AFTER RETURNING HOME, I EXPERIENCED A SECOND, GRAN MAL SEIZURE AND WAS TAKEN BY AMBULANCE BACK TO THE ER. I WAS GIVEN INTRAVENOUS DILANTIN, AND ADMITTED TO THE HOSPITAL WHERE I STAYED THURSDAY INTO FRIDAY. I WAS GIVEN MORE BLOOD WORK-UP, AN MRI, AND AN EEG. RESULTS ARE PENDING FOLLOW-UP VISITATION WITH THE NEUROLOGIST. IN THE HOSPITAL, I RECEIVED 300MG OF DILANTIN (PILL FORM), DAILY. ACCORDING TO THE TECHNICIAN AND NURSE, I WAS RELEASED FROM THE HOSPITAL BECAUSE THEIR INITIAL SCREENING OF MRI AND EEG DID NOT SHOW TUMOR, CLOTTING, OR BLEEDING IN THE BRAIN. THE NEUROLOGIST HAS PRESCRIBED 300MG OF DILANTIN (PILL FORM) TO BE TAKEN DAILY. I AM NOW RESTRICTED FROM DRIVING FOR A MINIMUM OF THREE MONTHS, PENDING MY RESPONSE TO MEDICATION. ALTHOUGH THE NEUROLOGIST HAS NOT SEEN THE MRI OR EEG RESULTS, I HAVE BEEN DIAGNOSED WITH HAVING COMPLEX-PARTIAL SEIZURE DISORDER. THE NEUROLOGIST IS RELUCTANT TO AFFIRM OR DENY GARDASIL AS A CATALYST TO GRAN MAL EVENTS. 6/16/09 Received hospital medical records for 6/11-6/12/2009. FINAL DX: partial complex seizures Records reveal patient experienced 2 tonoclonic seizures w/tongue biting on 6/10 lasting approx 3 min w/postictal period after. Seen in outlying ER where w/u WNL & d/c to home. Returned to ER after 2nd seizure, loaded w/antiseizure meds & transferred to higher level of care. Neuro consult done & revealed pt had stereotype espisodes x 3 years. Tx w/antiseizure meds. 8/3/09 Received ICD9 codes: 780.39.

Other Meds: NONE

Lab Data: TWO BLOOD WORK-UPS, CT SCAN, MRI, EEG 6/16/09 Received medical records for LABS: CT head, CBC, CMP all WNL.

History: NONE 6/16/09 Received medical records for PMH: sterotyped episodes x 3 years.

Prex Illness: NONE

Prex Vax Illns: NONE~ ()~~0~Patient|NONE~ ()~~0~Sibling|NONE~ ()~~0~Sibling

Vaers Id: **349112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Jun-2009	08-Jun-2009	0	15-Jun-2009	24-Jun-2009	FL		24-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2906AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1278X	1	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall

Symptom Text: Patient suddenly fell to the floor about 1 minute after.

Other Meds:

Lab Data: None

History: Allergic Rhinitis

Prex Illness: Abscess, L arm

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349120-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-May-2009	28-May-2009	0	15-Jun-2009	23-Jun-2009	IL		16-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1131X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disorientation, Dizziness

Symptom Text: Pt. was seen on 6/9/09 for pap smear - during course of visit she advised provider that she refused any further GARDASIL. Stated that apx 3 hours after 1st GARDASIL, she felt disoriented - family members claim she was "in and out of reality" - dizzy, disoriented lasted for 24 hours.

Other Meds:

Lab Data:

History: Hypothyroidism; Depression; Hx of overdose 2005; ETOH dependence

Prex Illness: None noted

Prex Vax Illns:

Vaers Id: **349128-1 (S)** **Related reports:** 349128-2; 349128-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-May-2009	31-May-2009	18	15-Jun-2009	18-Jun-2009	VA		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	2	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Ataxia, Back pain, Blood product transfusion, Cerebellar ataxia, Decreased appetite, Dysarthria, Dyskinesia, Dysphagia, Epistaxis, Fatigue, Gait disturbance, Headache, Malaise, Miller Fisher syndrome, Oropharyngeal pain, Pain in extremity, Pain in jaw, Pyrexia, Respiratory tract congestion, Swelling face, Upper respiratory tract infection, Viral infection, Vomiting

Symptom Text: 5/27/09 S.T. Congestion; 6/2/09 Fever, leg pain; 6/6/09 headache, vomiting; 6/10/09 - broad-based gait, facial weakness/? asymmetry. 7/21/09 Hospital records received 6/11/09 to 6/23/09. Assessment Post-viral cerebellar ataxia. Patient developed pharyngitis, fever, sinusitis. Severe headache, vomiting, fatigue, malaise. Evaluated at several other clinics, given antibiotics and IV fluids. Subsequently lost appetite, developed right facial swelling, difficulty eating, jaw pain, slurred speech, and a wide stance gait. Presented to the ER with ataxia, fatigue and malaise. Fever, throat pain, jaw pain, URI, vomiting, back and lower extremity pain and lethargy. Ill in appearance. Difficulty opening mouth. Difficulty swallowing. Wide based gait, difficulty tandem walking. Nosebleeds. Miller Fisher Syndrome? ICD-9 Codes: 781.3 357.0 112.0 578.0 783.0 787.20 461.0 477.9 784.7

Other Meds:

Lab Data: elevated CSF protein; Head CT and MRI normal. 7/21/09 Hospital records received 6/11/09 to 6/23/09. LABS and DIAGNOSTICS: CT Scan Head - no focal abnormalities. CSF - Protein 93 MG/DL (H), WBC 4 (H), NEUT 7% (H) LYMPH 85% (H) MONO 8% (L).

History: 7/21/09 Hospital records received 6/11/09 to 6/23/09. Allergic rhinitis. Augmentin causes vomiting.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **349128-2 (S)** **Related reports:** 349128-1; 349128-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-May-2009	27-May-2009	14	08-Jul-2009	09-Jul-2009	VA		23-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Dehydration, Dyskinesia, Fatigue, Gait disturbance, Gastroenteritis viral, Intensive care, Miller Fisher syndrome, Neurological symptom, Sinusitis, Speech disorder

Symptom Text: Patient came down w/ a "virus" then went into a sinus infection and then got a stomach virus all back to back over 2 weeks. Then presented neurological disfunctions in her facial muscles, speech, mouth motor skills, severe changes in her walking gait, extreme fatigue and dehydration. Took her into the ER. Within 36 hours diagnosed w/ Miller-Fisher Syndrome. Went into intensive care for several days and stayed in the hospital for total of 2 weeks. Still recovering and involved in physical, occupational and speech therapies multiple times per week and still on liquid thickeners.

Other Meds: None

Lab Data: Multiple blood workups, CT Scan, MRI, Lymes disease testing

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **349128-3 (S)** **Related reports:** 349128-1; 349128-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-May-2009	27-May-2009	14	08-Oct-2009	09-Oct-2009	VA	WAES0907USA05131	13-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	2	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Blood product transfusion, Dehydration, Facial paresis, Fatigue, Gait disturbance, Gastroenteritis viral, Head deformity, Headache, Intensive care, Miller Fisher syndrome, Motor dysfunction, Nervous system disorder, Pain in extremity, Pyrexia, Respiratory tract congestion, Sinusitis, Speech disorder, Viral infection, Vomiting

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 11 year old female patient with no pertinent medical history who on 13-MAY-2009 was vaccinated intramuscularly into the right arm with the third dose of GARDASIL (Lot # 659054/0315Y). On 27-MAY-2009, the patient experienced congestion; on 02-JUN-2009 patient had fever and leg pain; on 06-JUN-2009 the patient experienced headache and vomiting and on 10-JUN-2009, the patient experienced broad-based gait, facial weakness? and asymmetry. On an unspecified date, there were several exams performed; cerebrospinal fluid total protein was elevated, head computed axial tomography and magnetic resonance imaging were normal. The patient required an emergency room visit. The listing indicated that one or more of the events required hospitalization. The original reporting source was not provided. The VAERS ID # is 349128-1. Additional information has been received from a registered nurse concerning an 11 year old female patient who on 13-MAY-2009 at 4:00 pm was vaccinated with the third dose of GARDASIL. No other concomitant medications. On 27-MAY-2009 (previously reported as 31-MAY-2009) at 12:30 the patient went to the physician's office with a "virus" the she went into a sinus infection and then got a stomach virus all back to back over 2 weeks. Then she presented neurological dysfunctions in her facial muscles, speech, mouth motor skills, severe changes in her walking gait, extreme fatigue and dehydration. The patient was taken to the emergency room, and within 36 hours she was discharged with MILLER-FISHER syndrome. She went to the intensive care unit for several days and stayed in the hospital for two weeks. As of 15-JUN-2009, the patient was still recovering after intravenous immunoglobulin and involved in physical, occupational and speech therapies multiple times per week and was still on liquid thickeners. A standard lot check investigation has been finalized. All in-process quality ch

Other Meds: None

Lab Data: Head computed axial, normal; Magnetic resonance, normal; Diagnostic laboratory, multiple blood workups; Cerebrospinal fluid, elevated; Lyme disease assay

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349150-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0906USA00130	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Guillain-Barre syndrome

Symptom Text: Information has been received from a physician concerning a patient who on unspecified date was vaccinated with a dose of GARDASIL (LOT# not reported). The reporter said the patient experienced an AE involving GUILLAIN-BARRE Syndrome-like symptoms. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349151-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	02-Feb-2007	02-Feb-2007	0	15-Jun-2009	15-Jul-2009	CT	WAES0905USA03639	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Urticaria, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 19 year old female with sulfonamide allergy, allergy to PEDIAZOLE and AUGMENTIN, who on 02-FEB-2007 was vaccinated with the first dose of GARDASIL 0.5 ml, I.M., on 04-APR-2007 was vaccinated with the second dose of GARDASIL (lot# 653736/0014U) 0.5 ml, I.M. Concomitant therapy included YASMIN. The patient developed hives some time after receiving both dose 1 and 2. At some point the patient had to be hospitalized and was given I.V. BENADRYL and steroids. On 13-JUN-2007, the patient was vaccinated with the third dose of GARDASIL (lot# 656050/0245U) 0.5 ml, I.M. The physician did not know if the patient had a reaction after third dose. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy; Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **349152-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	25-Jan-2008	25-Jan-2008	0	15-Jun-2009	15-Jul-2009	MA	WAES0905USA02240	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anaphylactic reaction, Tremor, Vomiting

Symptom Text: Information has been received from a nurse concerning a female with no allergies who on 20-JUL-2007 and on 24-SEP-2007 was vaccinated IM 0.5 mL with the first and second doses of GARDASIL (lot# Not reported) respectively. It was unspecified if the patient had any adverse events after the first or second doses. On an unknown date, the patient received the third dose of GARDASIL (lot# not reported) IM 0.5mL. After the third shot, on 25-JAN-2008, the patient started "shaking" and vomiting. The patient went to the Emergency Room of a hospital and had "an anaphylactic reaction" while there. The patient was not admitted to that hospital but was "transferred" and admitted to another hospital for the "anaphylactic reaction". Subsequently, the patient recovered from the anaphylactic reaction while she was in hospital. In follow-up, it was reported the events happened in 2008 and patient's name and details could not be recalled. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349153-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0905USA00980	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Guillain-Barre syndrome

Symptom Text: Information has been received from a nurse practitioner concerning 3 children who was vaccinated with GARDASIL. The nurse practitioner reported that a mother of her patient informed her that 3 children in her patient's high school developed guillain-barre syndrome after receiving GARDASIL. The patient refused and did not get the GARDASIL for this reason. Upon internal review, Guillain-Barre syndrome was considered to be an Other Important Medical Event. Attempts are being made to verify the existence of an identifiable patient and reporter. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349154-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	14-Jul-2009	CT	WAES0906USA00258	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a teenage female who within the last two years (approximately 2007) was vaccinated IM with a dose of GARDASIL (route in the series and lot number unspecified). The physician reported that the patient "fainted" after getting the vaccine. The outcome of the patient was recovered. The patient sought unspecified medical attention. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 349155-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Sep-2006	15-Dec-2006	78	15-Jun-2009	14-Jul-2009	--	WAES0707USA01443	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received for the Merck pregnancy registry, from a nurse concerning a female patient, who was vaccinated with two doses of GARDASIL on 28-Sep-2006 and 27-Nov-2006 respectively. The patient is currently pregnant and her LMP was 15-Dec-2006. The patient's outcome was unknown. Follow-up information was received via the registered nurse from pregnancy questionnaire. The 17 year old patient with a history of 1 previous pregnancies and 1 full and a history of gestational diabetes mellitus was vaccinated with three doses of GARDASIL on 28-sep-2005 (lot # 653735/0688F), 27-Nov-2006 (lot # 653978/0955F) and 05-Oct-2007 (lot # 658282/0929U) respectively. Other medication use during pregnancy included prenatal VITAMIN. On 04-APR-2007, serum alpha-fetoprotein test was performed with negative delivered a male normal baby weighting 7 pounds 5.5 ounces with apgar score 9/9 at 36 weeks. The length of the baby is 19 inches. There were no congenital anomalies, other complication or abnormalities. There was no complication during pregnancy and labor/delivery. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 05/02/07, within normal limits; serum alpha-fetoprotein, 04/04/07, negative

History: Gestational diabetes mellitus

Prex Illness:

Prex Vax Illns:

Vaers Id: 349156-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	16-Jan-2008	16-Jan-2008	0	15-Jun-2009	14-Jul-2009	MO	WAES0803USA00128	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a registered nurse, for the pregnancy registry for GARDASIL concerning a 21 year old female with a history of laparoscopic cholecystectomy (27-JUL-2007) and cesarean section who on 16-JAN-2008 was vaccinated intramuscularly in the right deltoid with a dose of GARDASIL (lot#659439/1267U). There was no concomitant medication. The patient sought unspecified medical attention during an office visit on 16-JAN-2008 and 04-FEB-2008. The nurse reported that the patient was pregnant. Last menstrual period was 23-DEC-2007 and estimated date of delivery is 28-SEP-2008. The patient had a negative urine pregnancy test on 16-JAN-2008 and a positive pregnancy test on 04-FEB-2008. No symptoms have been reported. Follow up information received on 04-MAY-2009 from the registered nurse stated that the patient transferred her prenatal care to another physician. The reporter said that she does know that the patient did deliver her baby and had no complications. Follow information received from a physician indicated that the patient gave birth to a normal live born female, who weighted 6 lbs and 6 ounces on 13-SEP-2008 at 37 weeks and 3 days from LMP. The baby's length was 19" and her apgar score was 9/9. There were no congenital abnormalities. It was also reported that the baby experienced decreased fetal movements and decreased heart beat to beat variability. There were no complications during pregnancy and during labor. The patient had routine prenatal blood work within normal limits. No further information is available.

Other Meds: None

Lab Data: urine beta-human, 01/06/08, negative; urine beta-human, 02/04/08, positive

History: Cholecystectomy; Cesarean section

Prex Illness:

Prex Vax Illns:

Vaers Id: 349157-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-Dec-2007	12-Feb-2008	47	15-Jun-2009	14-Jul-2009	WV	WAES0804USA02086	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a physician for the Pregnancy Registry for GARDASIL, concerning a 17 year old female with no known allergies and a history of depression, iron deficiency anemia and gastroesophageal reflux who on 27-DEC-2007 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL (lot # 659435/1265U). On 25-FEB-2008 the patient was vaccinated intramuscularly in the "right upper arm" with a 0.5 mL second dose of GARDASIL (lot # 659962/1740U). The physician reported that on an unspecified date the patient called her OB/GYN and reported that she was approximately 8 weeks gestation. Actual LMP and method of pregnancy confirmed were not reported. In follow-up it was reported that concomitant medication included BENTYL, 10 mg as needed for the treatment of GERD; ORTHO TRI-CYCLEN, 0.025 mg daily for "prevention"; and ZOLOFT, 25 mg daily for the treatment of "Post Partum". It was also reported that the patient's estimated delivery date is 20-NOV-2008 (estimated LMP 12-FEB-2008). Follow-up information has been received that the patient made a preterm delivery on an unknown date, the infant was normal. No further information is available.

Other Meds: BENTYL, 10 mg; ORTHO TRI-CYCLEN, 0.025 mg; ZOLOFT, 25 mg

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 2/12/2008); Depression; Iron deficiency anemia; Gastroesophageal reflux

Prex Vax Illns:

Vaers Id: 349158-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	09-May-2008	09-May-2008	0	15-Jun-2009	14-Jul-2009	MA	WAES0806USA08328	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TTOX	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chlamydial infection, Drug exposure during pregnancy, Thrombocytopenia

Symptom Text: Information has been received from a Nurse Practitioner, for the Pregnancy Registry for GARDASIL, concerning a 19 year old female with thrombocytopenia who on 09-MAY-2008 was vaccinated intramuscularly with a first dose of GARDASIL (lot # 659437/1266U). Concomitant therapy included tetanus toxoid, administered "on the same day, 09-MAY-2008") and vitamins (unspecified). On an unspecified date the patient had a positive urine pregnancy test. The patient's LMP was reported as 08-APR-2008. The patient sought unspecified medical attention. Patient outcome was not reported. Follow up information has been received from a completed questionnaire by a certified nurse midwife (previously reported as nurse practitioner). It was reported on the questionnaire that the patient with no concurrent medical conditions, on an unspecified date experienced Chlamydia infection (2 episodes) and thrombocytopenia (previously reported as concurrent condition) during pregnancy (diagnostic tests performed on unspecified dates). Other medications used during this pregnancy included prenatal vitamins (unspecified) and azithromycin. On 22-AUG-2008, the patient had a screening ultrasound. On 10-JAN-2009 at 39 weeks from LMP, the patient delivered a male liveborn infant. He weighed 8 lbs and 03 oz, apgar score was 8/9. Additional information is not expected.

Other Meds: azithromycin; vitamins (unspecified)

Lab Data: ultrasound, 08/22/208, screening; diagnostic laboratory, chlamydia positive X2; urine beta-human, positive; platelet count, thrombocytopenia

History:

Prex Illness: Pregnancy NOS (LMP = 4/8/2008)

Prex Vax Illns:

Vaers Id: 349159-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Apr-2008	05-Jun-2008	63	15-Jun-2009	14-Jul-2009	AZ	WAES0807USA00352	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Drug exposure during pregnancy, Pyelonephritis

Symptom Text: Information has been received through the Merck pregnancy registry from a registered nurse concerning a 21 year old female with no pertinent medical history and no history of drug reactions or allergies who on 03-APR-2008 was vaccinated with the first dose of GARDASIL (lot#: 659964/1978U) 0.5 ml IV, and on 05-JUN-2008 was vaccinated with the second dose of GARDASIL (lot#:658556/1060U). Concomitant therapy included BENADRYL and ADVIL. After vaccination on 05-JUN-2008, the patient mentioned that she may be pregnant. On 05-JUN-2008, a urine pregnancy test confirmed the patient was pregnant. The patient's last menstrual period was 20-APR-2008, the estimated delivery date is 25-JAN-2009. The patient sought medical attention with a physician office visit. Follow up information received on 28-MAY-2009 from a registered nurse stated that the coach with seasonal allergies and a history of pyelonephritis and one previous pregnancy that resulted in spontaneous abortion on 05-JUN-2008 at 11:15 a.m. received the second dose of GARDASIL intramuscularly into the left deltoid. Concomitant therapy included BENARYL, vitamins unspecified, and MACROBID given for history of pyelonephritis. The patient was prescribed ADVIL for pain. The patient had a ultrasound on 25-JUN-2008 which confirmed the EDC on 02-FEB-2009 and a MSAFP on 21-AUG-2008, which was normal. On 04-SEP-2008 the patient developed pyelonephritis. Her outcome was not reported. On 06-FEB-2009 the patient gave birth to a normal female at 40 4/7 weeks from LMP, who weighted 7 lbs; her apgar score was 8/9. It was reported that there were no complications, during pregnancy and labor/delivery. There were no congenital anomalies. No further information is available.

Other Meds: BENADRYL; MACROBID; vitamins (unspecified)

Lab Data: ultrasound, 06/26/08, EDC=02-FEB-2009; urine beta-human, 06/05/2008, positive; serum alpha-fetoprotein, 08/21/08, normal

History: Pyelonephritis

Prex Illness: Pregnancy NOS (LMP = 4/20/2008); Seasonal allergy

Prex Vax Illns:

Vaers Id: **349160-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	14-Jul-2009	--	WAES0903USA00005	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Orthostatic hypotension

Symptom Text: Information has been received from a physician concerning four female patient's who were vaccinated with dose of GARDASIL. Subsequently the patients experienced postural hypotension. Unspecified medical attention was sought. At the time of this report, the outcomes were unknown. Follow up information was received from a physician concerning a female patient. The physician stated that after further discussions, it was decided that there was no relation to these events and the GARDASIL vaccination. The physician was confident that the patient was fine. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 349161-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	20-Feb-2009	Unknown		15-Jun-2009	14-Jul-2009	IL	WAES0903USA01240	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1496X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cystitis, Drug exposure during pregnancy, Influenza, Malaise

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a 21 year old white female with no significant past medical history or concurrent medical conditions and no previous pregnancies who on 20-FEB-2009 was vaccinated with the third dose of GARDASIL (Lot # 661954/1496X) by her obstetrician in another office. The patient's LMP was reported as 12-JAN-2009, EDD 19-OCT-2009. It was not reported whether the patients sought medical attention. Follow-up information was received from a registered nurse via phone call on 16-APR-2009 which reported that the patient told her that she had gotten GARDASIL during this pregnancy at a different office in another country. The patient was recently 13 weeks estimated gestational and had an EDD of 19-OCT-2009. According to the patient, the patient was told by her general practitioner that she should not breast feed this baby after birth, since she was exposed to the vaccine during pregnancy. The reporting registered nurse referred the patient to her obstetrician for further discussion. No further information was provided at this time. Follow-up information has been received from a pregnancy questionnaire. On an unspecified date in 2009, "during pregnancy", the patient experienced sickness, flu and bladder infections. The outcome was unknown. No other information was provided at this time. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Concurrent Conditions: Pregnancy NOS (LMP = 1/12/2009)

Prex Vax Illns:

Vaers Id: **349162-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Mar-2009	11-Mar-2009	0	15-Jun-2009	14-Jul-2009	NC	WAES0903USA01849	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	AC52B030AA	0	Left arm	Unknown	
	DTAP	SANOFI PASTEUR	1312X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Information has been received from a registered nurse concerning an 11 year old female who on 11-MAR-2009 was vaccinated with GARDASIL (lot number, route and site not reported). Concomitant therapy included DAPTACEL and LUPRON. The patient was to receive DAPTACEL and MENACTRA. It was not product confusion. It was a human error on the part of the nurse. Based on child's age the nurse thought GARDASIL was to be given. The patient's mother did not want the child to get GARDASIL. No adverse effects noted. The patient sought medical attention. Follow up information was received from consumer concerning her daughter. The mother stated her daughter would not continue with the 2nd or 3rd dose of GARDASIL. Follow-up information has been received from a health professional concerning the 11 year old female who on 11-MAR-2009 was vaccinated with the first dose of GARDASIL (lot number 661846/1312X, route not reported) into her right deltoids. Concomitant therapy included her first dose of DAPTACEL, (lot number AC52B030AA, route not reported) into her left deltoid. The patient has two siblings. Additional information is not expected.

Other Meds: LUPRON

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349163-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	23-Mar-2009	23-Mar-2009	0	15-Jun-2009	14-Jul-2009	IL	WAES0903USA04686	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect route of drug administration, Injection site pain

Symptom Text: Information has been received from a registered nurse concerning a 11 year old female who on 24-MAR-2009 was vaccinated with the first dose of GARDASIL subcutaneously instead of intramuscularly. No AE involved. The patient sought medical attention with physician. Follow up information was received from the registered nurse. It was reported the 10 year old (previously reported as 11 year old) patient with no known allergies or medical conditions who at approximately 12:45 pm on 23-MAR-2009 (previously reported as 24-MAR-2009) was vaccinated with the first dose of GARDASIL (lot # 661952/1129X) subcutaneously into the right arm instead of intramuscularly in error. At the same time, the patient complained of soreness at site. No labs or diagnostic tests were performed. At the time of reporting, the outcome was not reported. No further information was available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 349164-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-May-2008	19-May-2008	0	15-Jun-2009	14-Jul-2009	MN	WAES0904USA00153	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse for the pregnancy registry for GARDASIL concerning a 16 year old female, who on 26-FEB-2008 was vaccinated with the first dose of GARDASIL, on 19-MAY-2008, was vaccinated with the second dose of GARDASIL and on 08-OCT-2008, was vaccinated with the third dose of GARDASIL. The registered nurse reported that the patient received the GARDASIL vaccine while pregnant. The patient sought medical attention at the nurse's office. The estimated date of last menstrual period was 14-MAY-2008. The delivery date was 18-FEB-2009. The reporter stated that the pregnancy was normal and the baby was doing fine. Follow-up information was received from questionnaire completed by the registered nurse indicating that she was a patient with a history of 0 previous pregnancies, polycystic ovaries syndrome (so minimal ovulation's) and no concurrent medical conditions. The patient did not have infections or illnesses during pregnancy . Routine tests performed included: an ultrasound done at 28 weeks of gestation to track gestation age (first prenatal appointment); group B streptococcus test done 3 to 4 weeks before delivery resulting negative and a gestational diabetes test done at 30 to 32 weeks of gestation which resulted negative. Medication taken during pregnancy included children chewable vitamins taken daily since 28 weeks of gestation. The patient was not progressing past 8 centimeters. The patient gave birth to a normal female child, who weighted 8 pounds 3 oz. The baby did not have any congenital anomaly. Follow up information has been received from a physician via medical record which reported that the on 25-FEB-2009 the patient, the patient's mother and the baby went to the doctor's office. The baby's height was 20.5 inches. The baby was feeding with baby feeding formula (SIMILAC ADVANCED IRON) and baby drink 2-3 oz every 2-3 hours. The patient was still taking vitamins (physician suggested to take them until 6 weeks postpartum). Physician stated that the ba

Other Meds: vitamins (unspecified)

Lab Data: diagnostic laboratory 01/18/09 - Group B Streptococcus : negative; diagnostic laboratory - gestational diabetes: negative; ultrasound - To track gestation age - 28 wks.; physical examination 12/09/08 - weight: 143 pounds; physical examinati

History: Polycystic ovaries

Prex Illness: Pregnancy NOS (LMP = Unknown) Penicillin allergy

Prex Vax Illns:

Vaers Id: **349165-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Mar-2009	20-Mar-2009	0	15-Jun-2009	14-Jul-2009	NC	WAES0904USA01441	14-Jul-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	0651X	1	Unknown	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB260AA	1	Unknown	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a registered nurse, for the GARDASIL a Pregnancy Registry product concerning a 14 year old female patient who on 29-MAR-2007 was vaccinated with the first 0.5 mL IM dose of GARDASIL (lot # 654535/0960F) and on 20-MAR-2009 with the second 0.5 mL IM dose of GARDASIL (lot # 661703/0651X). Concomitant therapy included unspecified birth control pills, and on 20-MAR-2009 received MENACTRA), HAVRIX, and unspecified therapy for urinary tract infection. It was reported that on 20-MAR-2009 the patient received her second dose of GARDASIL and was pregnant. Her LMP was 23-FEB-2009 and her EDD was 09-DEC-2009. Laboratory test performed included urine pregnancy test with positive results. Follow-up information received on 01-MAY-2009 from an initial pregnancy questionnaire completed by the physician stated that the patient was a 14 year old Hispanic female, with no previous pregnancies, who on 20-MAR-2009, was vaccinated with the second dose of GARDASIL (lot # 661703/0651X). Concomitant therapy given on 20-MAR-2009 included MENACTRA, 0.5ml, BOOSTRIX, 0.5ml, HAVRIX, 0.5ml and BACTRIM, DS BID for urinary tract infection. Her last menstrual period was on 23-FEB-2009 and the estimated delivery date is 09-DEC-2009. The estimated conception date was 09-MAR-2009. It was reported that none prenatal testing had been performed at the time of the report. Follow up information received on 06-MAY-2009 from an initial and an outcome pregnancy questionnaire completed by the physician and the registered nurse stated that on 20-MAR-2009 the patient was vaccinated with the second dose of GARDASIL (lot # 661703/0651X). Concomitant therapy included MENACTRA, BOOSTRIX (lot # AC52B03AA), HAVRIX (lot # AHAVB260AA) and BACTRIM, DS BID for an uncomplicated urinary tract infection on 20-MAR-2009. Follow up information was received from a Registered Nurse (R.N.) who stated that the patient has not delivered as of 21-MAY-2009, her LMP was reiterated as 23-FEB-2009. Follow up information was received from a

Other Meds: hormonal contraceptives; BACTRIM DS TABLETS

Lab Data: urine beta - human - positive

History:

Prex Illness: Pregnancy NOS (LMP = 2/23/2009)

Prex Vax Illns:

Vaers Id: **349168-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Mar-2008	Unknown		15-Jun-2009	14-Jul-2009	ME	WAES0905USA00193	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT False positive laboratory result

Symptom Text: Information has been received from a medical assistant concerning a female who was vaccinate with on unspecified dates (doses and LOT# were not reported). When donating blood after vaccinated with GARDASIL the patient's parasite blood test showed positive for Chagas. Further testing showed the original test was false positive and she did not have Chagas disease. The patient was told that Chagas test showed positive was frequently see in patients that have vaccinated with GARDASIL. Follow-up information has been received via a phone call from the physician concerning a 17 year old female who was vaccinated with GARDASIL on unspecified dates (dose and LOT# were not reported). The patient attempted to donate blood and was told that she had a false positive confirmatory test for Chagas disease. It reported that the false positive test was related to the GARDASIL vaccination. Follow-up information has been received via a phone call from a medical assistant (M.A.) concerning the 17 year old female who on 06-AUG-2007, 15-NOV-2007 and 03-MAR-2008 was vaccinated with a dose of GARDASIL (LOT# not reported, 659435/1265U, 659182/1757U respectively). No other concomitant vaccines were given at the time of the GARDASIL doses. Additional information has been requested.

Other Meds: Unknown

Lab Data: parasite identification, false positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 349169-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-May-2008	01-May-2008	0	15-Jun-2009	14-Jul-2009	--	WAES0905USA00220	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Malaise, Nausea, Pain in extremity, Pyrexia

Symptom Text: Information has been received from a caller concerning her daughter a 17 year old who became very ill after receiving injection the first dose of GARDASIL on 01-MAY-2008. There was no concomitant medication. She had a fever, nausea, dizziness, and pain on the entire length of the arm where the injection was given. The patient sought medical attention and the outcome was unknown. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349170-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-Apr-2009	29-Apr-2009	1	15-Jun-2009	14-Jul-2009	--	WAES0905USA00239	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal tenderness, Asthenia, Dizziness, Dysuria, Fatigue, Pelvic pain, Urinary tract infection, Vaginal discharge, Vaginal haemorrhage, Vaginal infection, Vomiting

Symptom Text: Information has been received from a 20 year old female patient with parakeratotic cells evidenced in previous PAP test, who on 20-APR-2009 was vaccinated with the first dose of GARDASIL. On 29-APR-2009 the patient vomited after receiving the vaccine. The patient further stated that she was still feeling weak, tired and dizzy. The patient did not seek medical attention. It was reported that GARDASIL was discontinued. At the time of reporting the patient had not recovered. No further information is available. 7/13/09 Medical notes received DOS 4/28/09 to 6/30/09. Patient presented on day of immunization for follow-up of abnormal PAP. Abdomen tender on palpation. Subsequent visits:pelvic pain, irregular 'bleeds' with thick white discharge, burning urine. Vaginal infection, UTI.

Other Meds: Unknown

Lab Data: Unknown.

History:

Prex Illness: Parakeratosis 7/13/09 Medical notes received DOS 4/28/09 to 6/30/09. Abnormal PAP.

Prex Vax Illns:

Vaers Id: **349171-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2009	01-May-2009	0	15-Jun-2009	14-Jul-2009	--	WAES0905USA00270	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MMR	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer concerning herself with no previous pregnancies and no reported past drug history who on 01-MAY-2009 was vaccinated with a dose of GARDASIL. Secondary suspect vaccine given on the same day included MMR II (manufacturer unknown). There was no concomitant medication reported. It was reported that on 01-MAY-2009, in the evening after getting the vaccines the patient got really sharp belly pain. On 02-MAY-2009 a home pregnancy test was done and the result was positive. The last menstrual period of the patient was on 25-APR-2009 and the estimated delivery date was 30-Jan-2010. Additional information has been requested.

Other Meds: None

Lab Data: Beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP= 4/25/2009)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349172-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Apr-2009	16-Apr-2009	1	15-Jun-2009	14-Jul-2009	MI	WAES0905USA00342	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 17 year old female with no pertinent medical history reported and no known drug allergies who on 15-Apr-2009 at 11:30 am was vaccinated intramuscularly in the left arm with third dose of GARDASIL (lot number 661044/0548X). There was no concomitant medication. The following day, on 16-Apr-2009 at 11:30, the patient experienced hives. The patient recovered from the event on an unspecified date. No lab tests were performed. The patient did not seek medical attention. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349177-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		16-Jun-2009	17-Jun-2009	--	WAES0906USA01436	17-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Amyotrophic lateral sclerosis

Symptom Text: Information has been received from a hospice nurse concerning a 16 years old female with unknown drug allergies and unknown medical history who was vaccinated with the first dose of GARDASIL. Subsequently the patient was diagnosed with Amyotrophic Lateral Sclerosis (ALS) shortly after receiving the first dose of GARDASIL. The nurse learned of the patient's experience when her family called seeking hospice care for her. The family did mention that the first dose of GARDASIL caused that to the patient. Unspecified medical attention was sought. It was unspecified if laboratory studies were performed. At the time of the report, the patient had not recovered. The Amyotrophic Lateral Sclerosis was considered to be disabling. In follow-up with the representative, it was learned that no contact information is available. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349178-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Nov-2007	Unknown		16-Jun-2009	17-Jun-2009	FR	WAES0906USA01841	17-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute tonsillitis, Angina pectoris, Asthenia, Cyanosis, Disturbance in attention, Dizziness, Dyspnoea, Erythema infectiosum, Fatigue, Hyperventilation, Injected limb mobility decreased, Injection site pain, Myopericarditis, No reaction on previous exposure to drug, Pain in extremity, Pericardial effusion, Peripheral vascular disorder, Raynauds phenomenon, Tremor

Symptom Text: Case received from Health authority in a foreign country on 04-JUN-2009 under HA reference No. PEI2009011724. It was reported (according to information of the patient herself and the patient's parents) that an 18-year-old patient was vaccinated with a third dose of GARDASIL (lot #, injection route and site not reported) on 26-NOV-2007. Post vaccination she developed injection site reaction with pain and decreased limb mobility. Approximately 2 weeks post vaccination, the patient developed tremor of the hands, asthenia, tiredness, peripheral circulatory disorder, dizziness and impaired concentration. The patient was treated with beta blocking agents. In the beginning of 2008 she developed relapsing angina tonsillaris. All reported symptoms were ongoing, worsening respectively. On 07-SEP-2008 she was hospitalized due to hyperventilation syndrome with dyspnoea. On 17-SEP-2008 the patient was hospitalized again. Perimyocarditis was diagnosed. MRI showed a mild pericardial effusion. The patient was treated with ibuprofen and resting. Symptoms worsened and further cardiac diagnostics were carried out. In January 2009 final diagnosis of angina pectoris in the scope of microvascular dysfunction with persisting Parvovirus B19 infection was established. In the course patient developed "blue hands and toes" as well as pain in both feet. Raynaud's syndrome was suspected, but not verified through diagnostics including rheumatological check up (all normal findings). Concerning ongoing tremor exhaustive neurological examinations were carried out and showed all normal findings. Diagnosis of "increased physiologic tremor" was established. The patient presented to a natural healer and her condition improved under "detoxification" treatment. The final outcome was not reported. First and second dose of GARDASIL, both lot # not reported, administered on 13-APR-2007 and on 20-JUN-2007 respectively were well tolerated. Other business partner numbers include E2009-04684. No further information is available.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, mild pericardial effusion

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349179-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Oct-2007	Unknown		16-Jun-2009	17-Jun-2009	NJ	WAES0805USA01495	17-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0092U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a health professional for the pregnancy registry for GARDASIL concerning a female with a history of atrial septal defect repair at age seven, who on 07-OCT-2007 was vaccinated with GARDASIL (lot # 656371/0181U). On 7-Jan-2008 the patient was vaccinated with her second dose of GARDASIL (lot # 655322/0092U). On 06-May-2008 the patient received her third dose of GARDASIL (lot # 655322/0092U). It was reported that the patient was found to be pregnant later the same day the last vaccination was given. A laboratory report was received in the office of a positive pregnancy test from the hospital the same day the last dose of vaccine was administered. Patient did not report the pregnancy. No problems were reported. Follow-up information has been received from a certified medical assistant who said that the patient was actually not pregnant at the time of the shot. She was not specific about which dose she was talking about. She reported that they found out that the patient lost the pregnancy a few days before her shot and very early in the pregnancy. She was not sure if it was an elective termination or a spontaneous abortion (SAB). Upon internal review, elective termination or a spontaneous abortion (SAB) was determined to be an other important medical event.

Other Meds: None

Lab Data: Beta-human chorionic, positive

History: Atrial septal defect repair

Prex Illness:

Prex Vax Illns:

Vaers Id: **349180-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	16-Dec-2008	18-Mar-2009	92	16-Jun-2009	17-Jun-2009	FR	WAES0906USA01991	17-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1113U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chemotherapy, Mediastinal mass, Non-Hodgkins lymphoma

Symptom Text: Information has been received from a pharmacist concerning an adult female with allergy to house dust and molds and contraception use who on 16-DEC-2008 was vaccinated with the third dose of GARDASIL (lot#1113U, batch#NH10090, injection site not reported) into the upper arm. Concomitant therapy included unspecified hormonal contraceptives. On an unspecified date the patient developed mediastinum tumor and the diagnosis of Non-Hodgkin's-Lymphoma was established on 18-MAR-2009. At the time of reporting, the patient was still under treatment with chemotherapeutic scheme BEACOPP (bleomycin, etoposide, adriamycin, cyclophosphamide, vincristin, prednisolone, procarbazine) and had not yet recovered. The first dose and second dose of GARDASIL (lot#1113U, batch#NH10090) were administered on 24-JUN-2008 and on 18-AUG-2008. Toleration was not reported. Non-Hodgkin's-Lymphoma was considered to be an other important medical event by the pharmacist. This case was linked with case E2009-03044 (WAES0904USA02133) (same reporter, same vaccine, similar event, but different batch number). Other company numbers included: E2009-04717. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: House dust allergy; Mycotic allergy; Contraception

Prex Vax Illns:

Vaers Id: 349184-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Oct-2008	Unknown		16-Jun-2009	22-Jun-2009	--		23-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia areata, Alopecia universalis

Symptom Text: Developed Alopecia Areata Universalis beginning three days after receiving third GARDASIL booster, Tetanus with Pertussis injection, and Flu vaccine.

Other Meds: Corticosteroid injection into bald spots; steroidal cream applied to bald spots.

Lab Data: Physical examination by health care provider and examination and treatment from specialist - dermatologist.

History: Female with latex allergy.

Prex Illness:

Prex Vax Illns:

Vaers Id: **349185-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Feb-2009	27-Feb-2009	0	15-Jun-2009	14-Jul-2009	--	WAES0905USA00366	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Dyspnoea, Pain, Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female who on 27-Feb-2009 was vaccinated intramuscularly. 0.5ml, with the first dose of GARDASIL (lot# 661046/0546X). Concomitant therapy included montelukast sodium (MSD) and Ortho Evra. The patient experienced a cough after receiving GARDASIL on 27-Feb-2009. The patient was brought to the emergency room due to her difficulty in breathing. The patient sought medical attention by speaking to the nurse practitioner and recovered. Follow up information has been received from the office manager who reported that no other vaccines were given at the time of GARDASIL vaccines dose. It was confirmed that the patient was not admitted. Emergency room treat included Acetaminophen and Ibuprofen (dose and duration not reported) for fever and pain. The patient was discharged home in stable condition. The emergency room records stated, "Impression: Drug Reaction. No further information is expected.

Other Meds: Ortho Evra; Singulair

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349187-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-May-2009	02-May-2009	1	15-Jun-2009	14-Jul-2009	CA	WAES0905USA00380	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tremor

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female patient with a history of epstein-barr virus infection and lymphadenectomy on 8-JAN-2009 who was vaccinated with the first dose of GARDASIL on 01-MAY-2009 (lot#: 662300/0100Y). When the patient woke up on 02-MAY-2009 she experienced tremors. The nurse practitioner reported that the patient was still experiencing tremors periodically and is coming into the office on 4-MAY-2009. No further AE information provided. Unspecified medical attention had been sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Epstein-Barr virus infection; Lymphadenectomy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349189-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	PA	WAES0905USA00383	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vertigo

Symptom Text: Information has been received from a physician concerning a teenager female who was vaccinated with the first dose of GARDASIL in April 2007 and second dose in August 2007. There was no concomitant medication and medical history. In November 2007, the patient started experiencing vertigo. Unspecified lab diagnostic studies had been performed. The patient had sought unspecified medical attention. It was reported that therapy with GARDASIL was discontinued. At time of reporting, the patient was not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 349191-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Nov-2008	01-Jan-2009	57	15-Jun-2009	14-Jul-2009	NC	WAES0905USA00387	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Pain in extremity, Pallor, Paraesthesia, Skin warm

Symptom Text: Information has been received from a physician concerning a 15 year old female with PENICILLIN allergy and no pertinent medical history who was vaccinated with three doses of GARDASIL (lot # 659435/1265U, exp: 16-JUL-2010) 0.5 ml, intramuscular administration. She received the first dose on 19-MAY-2008, the second dose on 09-JUL-2008, and the third dose on 05-NOV-2008. Concomitant therapy on 19-MAY-2008 included doses of ADACEL (lot # not reported), and MENACTRA (lot # not reported), other concomitant therapy included FLONASE. Two or three months after the third dose of GARDASIL (lot # 659435/1265U), exp: 16-JUL-2010, in January or February 2009, the patient experienced redness and tingling to the distal aspect of the feet when standing upright and redness in the left calf after walking, "such as in a mall". The patient was seen in the office on 24-APR-2009 and blood work was obtained. Results of labs were as follows: antinuclear antibody (ANA) and rheumatoid factor (RF) were negative. Urine drug screen (at the mom's request because she thought her daughter was doing drug) was negative. Sedimentation rate (sed rate) was 4, hemoglobin was 12.9, white blood cell count was 6.5, and platelet count was normal. The patient was seen again on 04-MAY-2009, and there was significant erythema, pinkness, and warmth distally when the left leg was in a dependent position. The patient was referred to a vascular surgeon for further evaluation. At the time of reporting the patient's symptoms persisted. Additional information has been requested. 7/13/09 Medical records received DOS 4/24/09 to 5/4/09. Assessment: Pain in limb/Bilateral, unchanged. Patient presents with feet that turn red and skin stings when she stands for over 10 minutes. Pain in calf when she walks in the mall. Pins and needles sensation in feet. Feet are erythematous, blanches, great toes are warmer than rest of foot. Surgical referral suggested.

Other Meds: FLONASE

Lab Data: Serum ANA 04/24/09 - negative; serum rheumatoid factor 04/24/09 - negative; urine drug screen 04/24/09 - negative; erythrocyte 04/24/09 4 - ; hemoglobin 04/24/09 12.9 - ; WBC count 04/24/09 6.5 - ; platelet count 04/24/09 - normal

History: 7/13/09 Medical records received DOS 4/24/09 to 5/4/09. Penicillin allergy.

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349192-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2008	01-Apr-2008	0	16-Jun-2009	24-Jun-2009	MA		24-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Light headedness, dizziness since vaccine series completed one year ago. Fainted 6/4/09.

Other Meds:

Lab Data:

History: Migraines

Prex Illness: None

Prex Vax Illns:

Vaers Id: **349193-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jul-2008	09-Dec-2008	138	15-Jun-2009	15-Jul-2009	NY	WAES0905USA00500	04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Hot flush, Inappropriate schedule of drug administration, Influenza like illness, Nausea

Symptom Text: Information has been received from a registered nurse (RN) concerning a 17 year old female who on 24-JUL-2008 was vaccinated with the first dose (lot number: 660553/0070X) and on 16-DEC-2008 with the second dose (lot number:661703/0651X) of GARDASIL (route not reported). On 16-DEC-2008, the patient appeared at the doctor's office and complained of flu-like symptoms (dizziness, nausea and hot flashes) which started approximately 09-DEC-2008 (one week prior to the office visit). The patient received the second dose despite the symptoms. The physician performed a physical diagnosed fatigue and dizziness and sent the patient for blood work (not specified) the same day. The blood work results were all normal. Additional information is not expected.

Other Meds: None

Lab Data: Diagnostic laboratory, 12/16/08, Blood work results normal; Physical examination, 12/16/08, diagnosed fatigue and dizziness

History: Unknown

Prex Illness: Dizziness; Fatigue; Influenza like illness

Prex Vax Illns:

Vaers Id: **349194-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-May-2009	08-May-2009	0	16-Jun-2009	25-Jun-2009	TX		25-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **349195-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	03-Jun-2008	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0905USA00510	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a mother concerning a her daughter who on 3-JUN-2008 was vaccinated with her first dose of GARDASIL (dose, route and lot number not reported). The mother stated that after getting first dose, her daughter experienced headache. Therapy with GARDASIL was discontinued on 3-JUN-2008. It was not specified if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349200-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	04-May-2009	04-May-2009	0	15-Jun-2009	15-Jul-2009	NJ	WAES0905USA00521	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on 04-MAY-2009 was vaccinated with the first dose of GARDASIL (lot #: 661766/0652X). The patient did not receive any concomitant vaccines at that time. About 5 minutes after the vaccination the patient experienced fainted for about a "second" and regained consciousness. The patient rested for a few minutes and then had fully recovered. Unspecified medical attention had been sought. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349201-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	14-Jul-2009	CA	WAES0905USA00528	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with GARDASIL and experienced syncope, the patient fainted within 15 minutes of receiving GARDASIL. Subsequently, the patient recovered from syncope on the same day. No further information provided at the time of reporting. The patient sought medical attention with a physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349203-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0905USA00529	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Haemorrhage

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter who on an unspecified date was vaccinated with her first dose of GARDASIL (LOT# was not reported). Approximately one week after vaccination, the patient started bleeding. It was reported that the patient had not started or gotten her menstrual cycle quite yet but the reporter thought that bleeding could be her actual cycle since her daughter is 12 year old. No other adverse event was reported. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349206-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	OH	WAES0905USA00538	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Urticaria

Symptom Text: Information has been received from a doctor of osteopathic medicine (D.O.) concerning a female who on an unspecified date was vaccinated with the first dose of GARDASIL (LOT # was not reported). On an unspecified date, after vaccination the patient experienced injection site pain and a hive reaction. The patient also was reported as recovered on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349207-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-May-2009	01-May-2009	0	15-Jun-2009	15-Jul-2009	CT	WAES0905USA00561	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea

Symptom Text: Information has been received from a registered nurse concerning a 21 year old female with no pertinent medical history or drug reactions/allergies who "soon" before developing diarrhea on 01-MAY-2009 was vaccinated with the second dose of GARDASIL (lot # 661846/1312X) 0.5ml intramuscular administration. Concomitant therapy included SEASONIQUE, ascorbic acid, calcium, (unspecified), cyanocobalamin and minerals (unspecified) (+) vitamins (unspecified) (store brand WOMENS DAILY MULTIVITAMIN). On 01-MAY-2009 the patient experienced diarrhea. The first three days after onset were pretty bad. She called the office. The patient has diarrhea 3-4 times a day now. At the time of reporting, the patient was not recovered. Follow up information was received from a registered nurse concerning the 21 year old female student who on 01-MAY-2009 was vaccinated with the second dose of GARDASIL (lot # 661846/1312X) into the left deltoid. The patient had no illness at time of vaccination. On 01-MAY-2009, the patient complained with episodes of diarrhea 3-4 times a day from 01-MAY-2009 to 05-MAY-2009. She was advised to use IMODIUM, clear liquid diet and slowly advance to a bland diet. The patient was advised to call if symptoms unresolved. At time of reporting, the reporter had no further contact from the patient. It was unknown whether the patient recovered. Additional information has been requested.

Other Meds: ascorbic acid; calcium (unspecified); cyanocobalamin; SEASONIQUE; store brand WOMENS DAILY Vitamins

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349208-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Apr-2009	21-Apr-2009	0	15-Jun-2009	15-Jul-2009	OK	WAES0905USA00563	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Crying, Drug exposure during pregnancy, Muscle spasms, Ovarian cyst

Symptom Text: Information has been received from a medical assistant and the patient's mother, for GARDASIL, a Pregnancy Registry product, concerning an 17 year old female with depression (diagnosed 3 years ago) and history of a cyst on her ovary (diagnosed 2 years ago) who on 21-APR-2009 was vaccinated with a first dose of GARDASIL (lot number 661846/1312X) (injection site and route not reported). There was no concomitant medication. Prior to receiving the vaccination, the patient had a negative urine pregnancy test (approximately 21-APR-2009), the patient's mother reported that on 04-MAY-2009 the patient started complaining about bad cramps that were so bad that she started to cry. The patient's mother called the physician who advised the patient be taken to the hospital for evaluation. The patient was brought to the emergency room but she was not admitted to the hospital and she was diagnosed with an ovarian cyst. The patient's mother said a blood pregnancy test, a urine pregnancy test and an ultrasound determined the patient was pregnant. As of 05-MAY-2009, the patient was five weeks, 4 days pregnant (LMP 26-MAR-2009, EDDD 31-DEC-2009). The patient had an appointment with an OBGYN. The patient's bad cramps (ovarian cyst) persisted. Additional information has been requested.

Other Meds: None

Lab Data: Ultrasound, 05/04/09, positive for pregnancy; Urine beta-human, 04/21?/09, negative; Urine beta-human, 05/04/09, positive; Beta-human chorionic, 05/04/09, pregnant

History: Ovarian cyst

Prex Illness: Pregnancy NOS (LMP = 3/26/2009); Depression

Prex Vax Illns:

Vaers Id: **349209-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	21-Aug-2008	21-Aug-2008	0	15-Jun-2009	15-Jul-2009	AR	WAES0905USA00570	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a licensed practical nurse, for the Pregnancy Registry for GARDASIL (Lot # 659184/0843X), concerning a 25 year old female who on 21-AUG-2008 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. The patient's last menstrual period was 22-JUL-2008. 35 weeks from her LMP she gave a birth to a healthy baby on 24-MAR-2009. Currently she is breast feeding the baby. The patient had sought medical attention. Follow up information has been received from this practical nurse. She reported that she did not have any more information than what she had provided. Additional information is not expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP + 7/22/2008)

Prex Vax Illns:

Vaers Id: 349210-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		15-Jun-2009	14-Jul-2009	--	WAES0905USA00572	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Pain, Pain in extremity

Symptom Text: Information has been received from a 25 year old female certified medical assistant concerning herself that she was vaccinated IM with the third 0.5 ml dose of GARDASIL. Subsequently she experienced extreme arm pain, including shooting pain in her arm, and difficulty lifting her arm for 2 days and she recovered. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349229-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-May-2009	29-May-2009	1	16-Jun-2009	25-Jun-2009	CA		25-Jun-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	GLAXOSMITHKLINE BIOLOGICALS	0341Y	1	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2915AA	0	Right arm	Subcutaneously	
HEPA	MERCK & CO. INC.	0932X	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0100Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Erythema, Hypoaesthesia, Injection site erythema, Injection site swelling, Paraesthesia, Pruritus, Swelling

Symptom Text: Pt was given MENACTRA - Vaccine given 5/28/09 redness 5/29 then seen 5/31 in ER Hosp. for right arm swelling shoulder to hand - Numb/tingling hand - Vaccine site 3" redness - Dx cellulitis - RX KEFLEX - Symptoms improved over days 6/4 itchy dic - ed KEFLEX

Other Meds: PROVENTIL; ADVAIR

Lab Data:

History:

Prex Illness: Acute extrinsic rotator/Tendonitis

Prex Vax Illns:

Vaers Id: **349231-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Jun-2009	13-Jun-2009	10	16-Jun-2009	24-Jun-2009	AZ		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	2	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Rash 10 days post vaccination seen in office for rash. ATARAX Rx.

Other Meds: None

Lab Data: none except rapid strep screen & culture

History: PENICILLIN ALLERGY

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349233-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Jun-2009	01-Jun-2009	0	16-Jun-2009	25-Jun-2009	NY		25-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Oropharyngeal pain, Pain, Pyrexia

Symptom Text: Fever, chills, headache, sore throat achy arms and legs.

Other Meds:

Lab Data: Rapid Flu test negative

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349234-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jul-2008	02-Jul-2008	1	16-Jun-2009	25-Jun-2009	TX		16-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1604X		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C2889AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue

Symptom Text: Fatigue X 2 days

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **349236-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Jun-2009	09-Jun-2009	1	16-Jun-2009	24-Jun-2009	MN		24-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Dizziness

Symptom Text: Woke up at 2 AM on 6/9/09 with temp of 101.4 & feeling dizzy. As of 8 am was feeling better, temp gone.

Other Meds: ALLEGRA 30 mg; ORTHOTRI-CYCLIN

Lab Data:

History: Anemic

Prex Illness: None

Prex Vax Illns:

Vaers Id: **349262-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	05-Jun-2008	04-Jul-2008	29	16-Jun-2009	24-Jun-2009	MA		24-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Injected limb mobility decreased, Nerve injury

Symptom Text: One month after injection the patient woke up with loss of function in her left arm. Went to ER and for therapy. She was told it was nerve damage, undetermined cause. She had a soft cast and was out of work for 2 months.

Other Meds: none

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

Vaers Id: **349269-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Mar-2009	27-Apr-2009	33	16-Jun-2009	25-Jun-2009	CA		26-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acne, Arthralgia, Bronchitis, Fatigue, Muscular weakness, Myalgia, Oral contraception, Pharyngitis

Symptom Text: 1 month following 1st gardasil injection patient reports muscle weakness or pain, non-progressing. Also c/o fatigue. Medical records received DOS 5/27/09 to 6/16/09. Assessment: Acne vulgaris, fatigue, multiple joint arthralgia, acute bronchitis, acute pharyngitis. Patient presents with acne, generalized fatigue, muscle cramping all over, pain multiple joints, oral contraceptives. ICD-9 Codes: 706.1, 780.7, 719.49, 466.0. 462, V72.3

Other Meds: allegra D, veramyst. Oral contraceptives.

Lab Data: cbc, cmp, esr, arthritis panel all normal. Medical records received DOS 5/27/09 to 6/16/09. LABS and DIAGNOSTICS: WBC - Normal, HCT 36.2% CMP WNL, ESR 4, ANA (-), RF (-), ASOT 82. EBV IgG (+) IgM (-). Toxo (-). CMV (-) Cocci (-).

History: NKDA. Chickenpox. Medical records received DOS 5/27/09 to 6/16/09. Second dose Gardasil given 5/27/09 (Lot# 0100Y) no worsening of symptoms.

Prex Illness: Allergic rhinitis only.

Prex Vax Illns:

Vaers Id: **349283-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Apr-2009	24-Apr-2009	17	15-Jun-2009	15-Jul-2009	FL	WAES0905USA00707	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster, Pain, Rash pruritic, Scab

Symptom Text: Information has been received from a Certified Medical Assistant concerning a 14 year old female with no pertinent medical history who on 07-APR-2009 was vaccinated with the first dose of GARDASIL (lot#: 661952/1129X) 0.5ml IM left deltoid. On approximately 2.5 weeks after the first injection, it's approximately on 24-APR-2009 the patient experienced a rash on her back that was itchy and painful. There was no concomitant medication. The patient was seen by the primary care physician and was diagnosed with shingles. Patient did not express any concern or idea that the shingles was a result of the GARDASIL vaccination. The patient had no fever. The patient was placed on Valacyclovir hydrochloride, 500 mg, 3 times a day for 7 days (It was also reported that the patient was placed on Valacyclovir Hydrochloride, 500 mg, 2 three times a day for 7 days), experienced scabbing on her back. At the time of reporting the patient was recovering and no further information was available. Additional Information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349284-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Nov-2007	09-Nov-2007	0	15-Jun-2009	15-Jul-2009	WA	WAES0905USA00733	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a healthcare worker concerning her 18 year old daughter who was vaccinated with the third dose of GARDASIL and later experienced intermittent pain or achiness in the arm where she received GARDASIL. Follow up information has been received from the healthcare worker and a nurse. It was reported that the 16 year old patient on 20-APR-2007 was vaccinated with the first dose of GARDASIL (Lot# 657617/0384U), on 8-AUG-2007 was vaccinated with the second dose of GARDASIL (Lot# 655620/0171U) and on 9-NOV-2007 was vaccinated with her third dose of GARDASIL (Lot# 658560/1062U). After vaccinated the third dose of GARDASIL, the patient had pain in the arm where she received the GARDASIL and the pain was "on and off". The patient went on to receive the following vaccinations: MENACTRA, Lot# 02343AA, ADACEL, Lot# AC52B015AA and the first dose of HAVRIX, Lot# 1280F, all administered on 22-JAN-2008. The patient received the second dose of HAVRIX on 21-AUG-2008. Lot# 1280F. The nurse stated that the patient had an appoint to see the physician on 08-MAY-2009. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349286-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	04-Mar-2009	04-May-2009	61	15-Jun-2009	15-Jul-2009	--	WAES0905USA00944	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a 23 year old female who on 04-MAR-2009 was vaccinated with with second dose of GARDASIL. The patient had no medical history. It was reported that the patient had her period was right after getting the second dose of GARDASIL. On 07-MAY-2009, the patient reported that her period was 3 days late. The patient didn't know if she was pregnant and didn't do any pregnancy test yet. The patient did not seek medical attention. At the time of reporting, the patient had not recovered. No further information is available.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 349287-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	NJ	WAES0905USA00950	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Vaginal abscess

Symptom Text: Information has been received from a consumer concerning her daughter a 23 year old female with a history of eczema and Dairy allergies (cause of the eczema) who completed vaccination series of GARDASIL "just about a year ago". Concomitant therapy included omega-3 marine triglycerides, proboitics, and pure essential brand (Dr. Ashes Brand). The patient didn't experience any symptoms after the first or second dose of GARDASIL. Two days after the third dose the patient developed a vaginal rash during her menstruation the rash became worse. The patient also had "abscesses" that had developed on the outside of the vagina. She stated that the abscesses were caused from an e-coli bacteria. The patient had been test for sexually transmitted diseases, skin cultures, abscess cultures, and biopsies all of which had been negative. The mother also stated her daughter has not engaged in any sexual activity and could not identify a source for rashes. The patient had been placed on antibiotics that do not provide relief and was last prescribed a cortisone cream that states "has settled things a little bit this week during her period." The mother and her daughter believed in "doing everything natural and only received GARDASIL after it was highly recommended by a physician who is a friend of the family." The office manager at the gynecologist explained the patient didn't receive her vaccinations at their office and speculated that the vaccines were given either at school or by the patient's father, who is a physician. The patient was now visiting her physician about two times a week due to "flare ups" and was going to be seeing an infectious disease physician. The patient was not recovered. Additional information has been requested.

Other Meds: Omega-3 marine triglycerides

Lab Data: Biopsy, negative; Diagnostic laboratory, test for sexually transmitted diseases-negative; Skin and/or subcutaneous, negative; Abscess culture, negative

History: Eczema; Food allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **349288-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
63.0	F	18-Feb-2009	Unknown		16-Jun-2009	15-Jul-2009	--	WAES0905USA00985	04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site rash, Myalgia

Symptom Text: Information has been received from a 63 year old female patient who was on 17-DEC-2008 vaccinated with the first dose of GARDASIL 0.5 ML on bum. The patient experienced muscle pain, dizziness and rash at the injection after getting the second dose of GARDASIL on 18-FEB-2009. Concomitant therapy included Raloxifene hydrochloride, Sumatriptan, Paroxetine hydrochloride, Omeprazole (MSD), vitamin D6, Aspirin, Omega-3 marine triglycerides and Calcium. The patient had not recovered at the time of reporting. It's not reported that the patient sought any medical attention. Additional information has been requested.

Other Meds: Aspirin; Calcium (unspecified); Omega-3 marine triglycerides; Prilosec; Paxil; Evista; Imitrex (Sumatriptan); Vitamin D (unspecified)

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349289-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
37.0	F	25-Apr-2007	Unknown		16-Jun-2009	15-Jul-2009	CA	WAES0905USA01063	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0868F	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Papilloma viral infection

Symptom Text: Information has been received from a 36 year old female patient who in 2006 was vaccinated with the three doses of GARDASIL. The patient was now HPV positive. The consumer stated that she had only one partner in her life and she was vaccinated with GARDASIL before having sexual relations. The patient had not recovered. The patient contacted her physician. Follow up information has been received from the physician, who reported that the patient on 15-NOV-2006 was vaccinated with first dose of GARDASIL (Lot number 653736/0868F), on 26-JAN-2007 with the second dose of GARDASIL (Lot number 653736/0868F). The physician reported that on concomitant vaccines were given. The patient was last seen in the office in 2007, at which time her PAP smear was negative for HPV. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, HPV positive; Diagnostic laboratory, ?/?/07, HPV: negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349290-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Mar-2008	06-Mar-2008	0	16-Jun-2009	16-Jul-2009	--	WAES0905USA01064	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site pain, Lethargy

Symptom Text: Information has been received from a nurse concerning her daughter a 14 year old female with amoxicillin allergy and no other medical history who in June 2008, was vaccinated with her first dose of GARDASIL (site and route of administration not reported). In September 2008, the patient was vaccinated with her second dose of GARDASIL (site and route of administration not reported). Concomitant therapy included a low dose of hormonal contraceptives (unspecified) to regulate her periods. In June 2008, on the day she received her first dose of GARDASIL the patient experienced sore arm at the injection site. In September 2008, the day after received her second dose of GRADASIL the patient experienced lethargy, severe headache and sore arm at the injection site. The lethargy and severe headache lasted for 2 days, and during that time the patient could not attend to school. The patient's mother could not confirm that her daughter was not able to attend the school due to the event. Subsequently, the patient recovered from lethargy and severe headache. The patient did not seek medical attention. Follow up call information received from a medical office assistant and registered nurse revealed that on 06-MAR-2008 the patient received her first dose of GARDSIL (lot # 659962/1740U), and on 02-JUL-2008 received her second dose of GARDASIL. Sore arm at the injection site developed on the day that 1st and 2nd dose were received, 02-JUL-2008 and 06-MAR-2008, respectively; lethargy and severe headache the day after 2nd dose was received on 03-JUL-2008. The nurse also confirmed that no other vaccines were administered at the same time as the GARDASIL doses. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **349291-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-May-2009	06-May-2009	0	15-Jun-2009	15-Jul-2009	MI	WAES0905USA01104	04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DPP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Migraine, Panic attack, Respiratory rate increased, Syncope, Tremor

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 06-MAY-2009 was intramuscular vaccinated with her 05ml dose of GARDASIL. Suspect therapy given on the same day included VAQTA (manufacturer unknown). Concomitant therapy included DTAP and MENACTRA. Subsequently the patient fainted and fell on the ground, when the patient came to, she had a migraine. She had a panic attack which included shaking and breathing fast. The patient had sought medical attention. The patient had recovered by the report time. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349292-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0905USA01112	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a pharmacist who heard from a nurse (mother of the patient) concerning the female patient who on unspecified dates was vaccinated with all three doses of GARDASIL (lot# were not reported). On an unspecified date, the patient experienced dermatological warts (not genital, only dermatological). It was reported that the patient did not seek medical attention and also was reported that the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349293-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-May-2009	01-May-2009	0	15-Jun-2009	15-Jul-2009	--	WAES0905USA01140	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Drug exposure during pregnancy

Symptom Text: Information has been received from a 23 year old female with no medical history or drug allergy who on 01-May-2009 was vaccinated with the first dose of GARDASIL and found out later she was pregnant. Concomitant therapy included Flagyl. The patient stated that her original visit to the practice was because she thought she was pregnant, however after a urine test the office stated she wasn't and administered the vaccine. The patient reported after getting the vaccine she started experiencing some abdominal pain and went for testing again and found out she was pregnant. The patient had "blood work" performed. At the time of the report the patient was recovered. No further information is available.

Other Meds: Flagyl

Lab Data: Diagnostic laboratory, blood work, pregnant ; Urine beta-human, 05/01/09, negative

History:

Prex Illness: Pregnancy NOS (LMP) = Unknown

Prex Vax Illns:

Vaers Id: **349294-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	09-Mar-2009	09-Mar-2009	0	15-Jun-2009	15-Jul-2009	CT	WAES0905USA01261	06-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle twitching

Symptom Text: Initial and follow up information has been received from a registered nurse concerning a 27 year old female with penicillin allergy and no pertinent medical history or concurrent conditions who on 09-Mar-2009 was vaccinated with the first dose of GARDASIL (lot# 661703/0651). 0.5ml, intramuscular administration. There was no concomitant medication and no other vaccines given with the GARDASIL that day. On 10-Mar-2009 the patient experienced facial cheek twitch. ("one of her cheeks had a little twitching for a week"). The patient did not report the adverse event until she came to the office for her second dose of GARDASIL. The doctor determined that the second dose of GARDASIL was discontinued. It was reported that the patient was recovered a week after it started. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: 349295-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Aug-2008	01-Sep-2008	13	15-Jun-2009	15-Jul-2009	CO	WAES0905USA01306	19-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Decreased appetite, Dyspnoea, Fatigue, Feeling cold, Headache, Mood swings, Musculoskeletal chest pain, Myalgia, Oropharyngeal pain, Persistent generalised lymphadenopathy, Tachycardia

Symptom Text: Information has been received from a physician concerning a female patient about 20 years old who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that 2 months after GARDASIL the patient developed fatigue and generalized adenopathy. The patient consulted with the physician. It was reported that the patient had not recovered at the time of the report. Additional information has been requested. This is in follow-up to report (s) previously submitted on 6/12/2009; 6/18/2009; 6/30/2009. Information has been received from a physician concerning a female patient about 20 years old who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that 2 months after GARDASIL the patient developed fatigue and generalized adenopathy. The patient consulted with the physician. It was reported that the patient had not recovered at the time of the report. Information has been received from a physician via medical record concerning an 19 year old white student patient with allergy to apricots, cherries and almonds, a non smoker, rare alcohol user, she was sexually active and did have safe sexual practices, she was an immune competent patient, right handed and history of migraines, eczemn and cat scratch disease who on 15-AUG-2008 and in November 2008 was vaccinated with the first and second dose of GARDASIL. Other medications included ZYRTEC for which had been on for 8 years and birth control pills (unspecified) over the last year. The patient was evaluated for ongoing fatigue and intermittent adenopathy. It was reported that in September had developed a sore throat and question if the diagnosis had been a strep throat. She had been ill for about two weeks with arthralgias and myalgias. Just feeling poorly and subsequently after that developed bilateral rib pain that she felt was at the level of the ribs themselves. It was reported that she had not been doing any excessive coughing, but just had ongoing pain. At that particular time, did not receive any antibiotic th

Other Meds: ZYTREC; hormonal contraceptives

Lab Data: body temp 101 degrees F - ; serum antistreptolyein - positive

History: Migraine; Eczema; Cat scratch disease

Prex Illness: Fruit allergy; Non-smoker; Alcohol use; Sexually active

Prex Vax Illns:

Vaers Id: **349296-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Oct-2008	01-Oct-2008	0	15-Jun-2009	15-Jul-2009	--	WAES0905USA01307	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Genital swelling

Symptom Text: Information has been received from a nurse practitioner concerning a female who in October 2007, was vaccinated with the first dose of GARDASIL. Subsequently the patient developed swollen labia on both sides. The patient still had swollen labia but only on one side by the report time. The patient had sought medical attention. Follow up information has been received from this nurse practitioner concerning this 21 year old female who in October 2008 (not 2007 as previously reported) was vaccinated with the first dose of GARDASIL. Subsequently the patient had labia swelling on the left side and had no pain. The patient was treated with medication and had a follow-up visit scheduled with the nurse practitioner in two weeks. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349297-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Mar-2009	08-Mar-2009	0	15-Jun-2009	15-Jul-2009	SC	WAES0905USA01432	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nasal congestion, Urticaria

Symptom Text: Information has been received from a nurse manager concerning a 25 year old female who on 08-MAR-2009 was vaccinated with GARDASIL. There was no concomitant medication. Subsequently the patient developed hives and felt the sensation of the right nostril closing up throughout the night of vaccination onto the next day. She was seen on 09-MAR-2009 at her primary care and was prescribed a (MEDROL DOSEPAK). Patient is inquiring about continuing the GARDASIL series. At this report time the patient had recovered. Follow up information has been received from this nurse manager: Their office did not perform any lab/diagnostic tests. The events did not require hospitalization, and were not disabling or life threatening. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349298-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	NY	WAES0905USA01443	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female who on an unspecified date was intramuscular vaccinated with GARDASIL. Subsequently the patient immediately after fainted. The office called an ambulance. The patient had sought medical attention. Follow up information has been received from an office administrator. He reported that a couple of months ago a girl who got "several vaccines" (not specifically GARDASIL) got dizzy after the shots. An office employee called the ambulance by mistake. The girl was not transported any where, and she didn't faint. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349299-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Aug-2007	Unknown		15-Jun-2009	15-Jul-2009	IN	WAES0905USA01447	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702F	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oropharyngeal pain, Rash generalised

Symptom Text: Information has been received from a licensed practical nurse concerning her 16 year old daughter with DURICET allergy and no pertinent medical history who on 03-AUG-2007 was vaccinated with the first dose of GARDASIL (Lot # 653650/0702F). There was no concomitant medication. Subsequently, sore throat was experienced first followed by the rashes all over her body in August 2007. After rash appeared, strep was ruled out, but the patient was still given (LEVAQUIN) for sore throat. The patient recovered from the sore throat in August 2007, but did not recover from the rash until mid-September 2007. The rashes lasted for 1 month. The patient sought medical attention by contacting physician. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **349300-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0905USA01464	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	By Mouth	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Colposcopy, Incorrect route of drug administration, Papilloma viral infection

Symptom Text: Information has been received from a female who in 2006 was vaccinated orally with GARDASIL and just recently had been diagnosed with human papillomavirus. The patient was not sure what type but was upset to find out she now had human papillomavirus. The patient experienced colposcopy but the result was unknown. The patient sought unspecified medical attention and outcome was unknown. The patient refused to provide any demographics. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349301-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Apr-2009	09-May-2009	17	15-Jun-2009	15-Jul-2009	--	WAES0905USA01625	17-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Crying, Fatigue, Headache, Inappropriate schedule of drug administration, Malaise, Sinusitis, Skin warm

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with lactose intolerance and not other drug reactions or allergies who was vaccinated with the first two doses of GARDASIL "sometime in 2007". After both doses she did not feel well. On approximately 22-APR-2009, "three weeks ago", the patient was vaccinated with the third dose of GARDASIL. There was no concomitant medication. On the night of 09-MAY-2009 the patient started to have a headache and stomach aches. In the past three days her stomach issues and headache have gotten worse, that she came home crying on 12-MAY-2009 because of the pain. As of 13-MAY-2009, "today", the patient was still experienced these symptoms and now she also felt hot to touch but did not have a fever. It was also reported that the patient just got her menstrual cycle and was going on three days of having that . No lab tests were done. The physician was called and unspecified medical attention was sought. The reporter was not sure the experiences the patient was having was from GARDASIL. Additional information has been requested.Records received 7/2/09-on 5/9/09 C/O headache, feeling feverish, stomach ache, tiredness, office note for 5/22/09-seen for C/O sinusitis no further visits.

Other Meds: None

Lab Data: None

History:

Prex Illness: Lactose intolerance

Prex Vax Illns:

Vaers Id: **349302-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-May-2009	08-May-2009	0	15-Jun-2009	15-Jul-2009	--	WAES0905USA01633	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2842AA		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C3032AA		Unknown	Unknown	
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Mobility decreased, Oedema peripheral, Pain in extremity

Symptom Text: Information has been received from a physician, a consumer and a secretary concerning a 15 year old female patient with no history of allergies who on 08-MAY-2009 was vaccinated with the first dose of GARDASIL in her right arm. Almost immediately the patient felt like that she had no circulation and no blood flow. She experienced numbness, pain all down the arm and hand, and she had the inability to move and her hand became swollen. The patient's mother reported that the patient could not use her hand. There was no rash or itching and no systemic symptoms. On 11-MAY-2009 the patient went back to see her physician. The physician stated that it was GARDASIL that was causing the experience and she should not get any more doses of GARDASIL. The physician did not offer any treatment nor did he do any treatment. On 14-MAY-2009 the patient's hand was still swollen and had pain, but there was no more pain in her arm. The patient's mother gave the patient ADVIL 200 mg which seemed to help. The patient's mother reported that she was going to take the patient back to see the physician. The outcome for other adverse events was unknown. Follow up information was received from the physician which reported that on 08-MAY-2009, the patient with no pertinent medical history and no known drug allergy received four different vaccines. The patient was given GARDASIL (lot # 661766/0652X) and RECOMBIVAX HB (manufacturer unknown, lot # AHBVB663AA) in the right arm, ADACEL (lot #C3032AA) and MENACTRA (lot # U2842AA) in the left arm. On 11-MAY-2009, the patient came back to the office complaining of right arm pain and swelling. There was no redness and only minor swelling. No treatment was given, and cold compresses were suggested. On 18-MAY-2009, the patient again returned to the office complaining of right arm pain. The patient was seen by another physician who noted normal findings, but referred the patient to a neurologist. The physician could not say if the condition was disabling, but did say that the patient was

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349303-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-Apr-2009	25-Apr-2009	2	15-Jun-2009	15-Jul-2009	CO	WAES0905USA01662	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pruritus, Rash pruritic

Symptom Text: Information has been received from a medical assistant concerning a 21 year old female with no allergies or medical history who was vaccinated intramuscularly, 0.5 ml, with the first dose of GARDASIL (Lot # 661766/0652X) on 23-FEB-2009, and with the second dose of GARDASIL (Lot # 661766/0652X) on 23-APR-2009. There was no concomitant medication. The patient called the physician on 28-APR-2009 and reported that on 25-APR-2009 she developed a rash on her shoulders, back and hands. The patient also reported she felt dizzy but none of the symptoms started until 2 days after getting GARDASIL. The patient reported the rash looked like red dots and were itchy. The physician prescribed (BENADRYL) for the itch. The physician advised the patient not to get the third dose of GARDASIL. The patient sought medical attention by calling office and was recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349304-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
33.0	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	CA	WAES0905USA01665	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Syncope

Symptom Text: Information has been received form a physician concerning his 33 year old daughter who had been vaccinated with GARDASIL series. During one of the GARDASIL vaccination (unspecified which dose), she developed syncope. She had sought medical attention and had recovered from syncope. No further information is available.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349305-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-Feb-2009	01-Mar-2009	2	15-Jun-2009	15-Jul-2009	CA	WAES0905USA01684	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on 27-Feb-2009 was vaccinated with the first dose of GARDASIL IM 0.5ml. On 01-Mar-2009 the patient developed a facial rash. There was no concomitant medication. On approximately 22-Mar-2009, after 2-3 weeks the rash resolved without treatment. The patient mentioned this adverse reaction on 13-May-2009, when she came to the office for her second dose of GARDASIL. No further information provided at the time of reporting. Follow up information has been received from another health professional reported that the 17 year old female patient was vaccinated with the second dose of GARDASIL (lot#: 661046/0546X) with an expiration of 01-Dec-2010 on 13-May-2009 and it was the only vaccine she received that day. It was confirmed that the patient recovered. No additional information is expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349306-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0905USA01721	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Complex regional pain syndrome

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with GARDASIL. Subsequently the patient experienced complex regional pain syndrome number 1, that is, regional pain after vaccination. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349307-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	06-May-2009	06-May-2009	0	15-Jun-2009	15-Jul-2009	CA	WAES0905USA01879	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Injection site reaction

Symptom Text: Information has been received from a physician concerning a 21 years old female with no pertinent medical history who was vaccinated with GARDASIL (lot#, dose, route and site of administration not reported) by a physician's assistant at the office on 05-MAY-2009 or 07-MAY-2009. The patient experienced headache, dizziness and an injection site reaction several hours after getting the vaccine. The patient was told to take ACETAMINOPHEN (manufacturer unspecified). Subsequently, the patient recovered. Additional information has been requested.

Other Meds: TYLENOL

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349308-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Feb-2009	05-Feb-2009	0	15-Jun-2009	15-Jul-2009	--	WAES0905USA01888	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1496X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse in a physician's office and a registered nurse in a county health department, for the Pregnancy Registry for GARDASIL, concerning a 21 year old female with a history of gestational diabetes with her first child and no drug reactions/ allergies who on 05-Feb-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL (lot# 661954/1496X) in the physician's office. There was no concomitant medication. It was reported that the patient did not have a pregnancy test prior to the vaccination. Subsequently, the patient discovered that she was pregnant. The patient's last menstrual period was 03-Jan-2009, her estimated delivery date is on 10-oct-2009. On 05-Mar-2009, the patient had a prenatal ultrasound performed in the physicians office that reported her estimated date of confinement (EDC) to be 19-Oct-2009. The nurse also reported that along with the prenatal lab work the patient had preformed, she also underwent a 1 hour glucose test that she failed. She then underwent a 3 hour glucose tolerance test that was normal. The patient was referred to a county health department. Additional information has been requested.

Other Meds: None

Lab Data: Ultrasound, 03/05/09, EDC 10/19/2009; Diagnostic laboratory, 03/05/09, Prenatal lab work(results not reported); Plasma glucose test (1. 03/05/09, failed; Plasma glucose test (3. 03/05/09, normal

History:

Prex Illness: Gestational diabetes

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349309-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	08-May-2009	08-May-2009	0	15-Jun-2009	15-Jul-2009	CA	WAES0905USA01902	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness, Nausea, Syncope

Symptom Text: Information has been received from a medical assistant concerning a 26 year old female who on 08-MAY-2009 was vaccinated with her first dose of GARDASIL. Subsequently the patient fainted. The patient has sought medical attention and had recovered. Follow up information has been received from this medical assistant concerning this 26 year old patient who was vaccinated with her first dose of GARDASIL (Lot# 660555/0279X). The patient did not received ant concomitant vaccines at report time. After receiving GARDASIL the patient stool up an fell down and lost consciousness. In the same day the patient regained consciousness. The patient had a "bump" on the right side of her forehead. The patient was nauseous. The patient has a "skull x-ray" which revealed no fracture. An ice-pack was applied to the right side of the patient's head. The physician's office contacted the patient on 09-MAY-2009. The patient stated that she felt fine. Additional information has been requested.

Other Meds: Unknown

Lab Data: skull x-ray, 5/8/09, no fracture

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349310-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0905USA01923	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician's assistant who reports an office had several patients faint after receiving GARDASIL. It was unknown exactly how many patients or time frame involved. The outcome of the patients was unknown. Follow up information was received from a office manager who said that their office was aware that "patients might faint when they get their GARDASIL vaccine" and that "patients faint all the time", therefore she was uncertain for the reason of the original report. She explained that details regarding individual patients would have to be discussed with the physician or physician's assistant upon their return. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349311-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-May-2009	09-May-2009	5	15-Jun-2009	15-Jul-2009	MI	WAES0905USA02012	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a medical assistant, for GARDASIL, a Pregnancy Registry Product, concerning a 17 year old female who was vaccinated with the first dose of GARDASIL on 02-FEB-2009, the second dose on 04-MAY-2009 IM 0.5 ML right deltoid (lot#: 0151). There was no concomitant medication. On 09-MAY-2009 the patient experienced a warm, swollen and painful injection site reaction and returned to the office on 12-MAY-2009. The patient was instructed to treat the area with cold compresses. On 14-MAY-2009, the patient took a pregnancy test and it was positive. The medical assistant did not have the patient's Last Menstrual Period date or Estimated Delivery Date. Subsequently the patient recovered from the injection site reaction on an unspecified date. The medical assistant did not know the name of the patient's OBGYN physician and no other detail at the time of reporting. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, 05/14/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349312-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	11-May-2009	Unknown		15-Jun-2009	15-Jul-2009	NY	WAES0905USA02013	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash

Symptom Text: Information has been received from a nurse concerning a 24 year old female who on 11-MAY-2009 was vaccinated with a 0.5 mL first dose of GARDASIL (lot # 661953/1130x), intramuscularly. The patient developed a rash at the injection site about 6 inched in diameter. No laboratories studies performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349313-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-May-2009	14-May-2009	0	15-Jun-2009	15-Jul-2009	AR	WAES0905USA02018	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	661764/0650X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness

Symptom Text: Information has been received from a certified medical assistant concerning a 14 year old female with no pertinent medical history who on 14-May-2009 was vaccinated with the first dose of GARDASIL (lot# 661764/0650X), o.5ml, intramuscular administration. There was no concomitant medication. On 14-May-2009 the patient "passed out" immediately after the vaccination. Subsequently, the patient recovered without requiring treatment and was released to home fully recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349314-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0905USA02021	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes simplex

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who in 2008 started the series of GARDASIL. Concomitant therapy included (ADVAIR), (CELEXA), (ATIVAN) and hormonal contraceptives (unspecified). It was reported that the patient tested positive for herpes simplex virus after receiving all three doses of GARDASIL vaccine. The patient did not have any symptoms of herpes simplex, but HSV IgG and IgM test showed positive. The patient was seen by the nurse practitioner for medical attention. At the time of reporting the patient had not recovered. Additional information has been requested.

Other Meds: CELEXA; ADVAIR; hormonal contraceptives; ATIVAN

Lab Data: serum Herpes simplex, positive; serum Herpes simplex, positive

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349315-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	IN	WAES0905USA02029	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a receptionist concerning her daughter who on an unknown date was vaccinated with a dose of GARDASIL (lot no. and route not reported). The receptionist reported the patient experienced HPV after receiving the vaccine. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 349316-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	17-Apr-2009	17-Apr-2009	0	15-Jun-2009	15-Jul-2009	GA	WAES0905USA02230	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hot flush, Laboratory test normal

Symptom Text: Information has been received from a certified medical assistant concerning a 25 year old female patient who on 17-APR-2009 received the first dose of GARDASIL (lot#661531/1311X) IM in her left arm. Concomitant therapy included NASONEX, hormonal contraceptives (unspecified) and ZYRTEC. On 17-APR-2009 the patient experienced hot flashes. The patient sought medical attention through an office visit. The patient's hot flashes persisted. Follow up information was received from a certified medical assistant on 27-MAY-2009. It was reported that the patient "would go ahead with doses #2 and #3." No other information regarding the AE was reported. On 28-MAY-2009, the certified medical assistant reported the following additional details: the patient had an allergy to ALUPENT, dust and pollen; no pertinent medical history; no other vaccines given at the time of the GARDASIL vaccination on 17-APR-2009; exact adverse event onset date was unknown, the patient simply reported at the 18-MAY-2009 office visit that she had been having hot flashes; some routine labs (not specified) drawn that day were all normal; hot flashes coincided with a new work-related stress, but did not go away when the work situation resolved; physician indicated that there was no correlation between the hot flashes and GARDASIL use; patient had to go to the office soon for the second GARDASIL dose; the patient after speaking with a co-worker, was interested in learning her "sugar level" so would see her primary physician. Additional information has been requested.

Other Meds: ZYRTEC, hormonal contraceptives, NASONEX

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity; House dust allergy; Pollen allergy

Prex Vax Illns:

Vaers Id: **349317-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	MA	WAES0905USA02247	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Wheezing

Symptom Text: Information has been received from a nurse concerning a female who on an unknown date, was vaccinated IM with the first dose of GARDASIL 0.5mL (lot# not reported). Subsequently the patient experienced wheezing. The patient went to the hospital but it was unspecified if the patient was admitted or not. The patient didn't complete the series of GARDASIL because of this adverse event. Therapy with human papillomavirus vaccine was discontinued. Subsequently, the patient recovered from wheezing. In follow-up, it was reported the events happened in 2008 and the patient's name and details could not be recalled. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349318-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	CT	WAES0905USA02253	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Headache

Symptom Text: Information has been received from a physician concerning a 15 year old female with a history of headaches who on unspecified dates were vaccinated with three doses of GARDASIL. (LOT# were not reported). No other vaccines were given at the time of the GARDASIL doses. It was reported that after each dose, the patient's headaches progressively got worse and required an unspecified medical attention. The patient's outcome was unknown. Follow-up information has been received from a nurse concerning the 15 year old female who was new to their office and was seen for the first time in their office on 18-MAY-2009. The nurse did not have any information regarding the vaccination because it was given elsewhere. The patient was not present with headache at time of the visit. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Headache

Prex Vax Illns:

Vaers Id: **349319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Mar-2009	18-Mar-2009	0	15-Jun-2009	15-Jul-2009	NC	WAES0905USA02260	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure increased, Dizziness, Dysarthria

Symptom Text: Information has been received from a physician and a registered nurse concerning an 18 year old female who on 18-Mar-2009 was vaccinated with the first 0.5ml dose of GARDASIL (659655/0940X, site not reported). There were no concomitant vaccines administered with GARDASIL. The patient experienced slurred speech, elevated blood pressure and felt light headed after receiving GARDASIL. The patient had sought unspecified medical attention. It was unknown if the patient was hospitalized. The patient was not scheduled for a follow-up visit to see the physician and was not going to complete the vaccination series. She recovered after 3 days on approximately 21-Mar-2009. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349320-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	16-Apr-2009	16-Apr-2009	0	15-Jun-2009	15-Jul-2009	--	WAES0905USA02572	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female who on 20-OCT-2008 was vaccinated with the first dose of GARDASIL. The second dose of GARDASIL was given on 04-FEB-2009. The third dose of GARDASIL was given on 16-APR-2009. On 21-APR-2009, the patient was seen by a provider because she presented with a generalized rash. She was treated with (ZYRTEC) and (CALRITIN). At the time of reporting, the outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349321-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	18-May-2009	19-May-2009	1	15-Jun-2009	15-Jul-2009	--	WAES0905USA02728	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure increased, Chest discomfort, Neck pain

Symptom Text: Information has been received from a licensed practical nurse concerning her 25 year old female friend who on 18-MAY-2009 was vaccinated with her first IM dose of GARDASIL (lot # not reported), for an unknown reason. The patient's relevant medical history includes an allergy to penicillin. She has no relevant concomitant medications or past drug history. On 18-MAY-2009, she received the first injection of the GARDASIL series in the right deltoid. On 19-MAY-2009, she began to feel chest pressure, achiness in her neck and a slightly elevated blood pressure. It is unknown if any relevant laboratory testing was performed. On 19-MAY-2009, it is unknown if she will continue, receiving the GARDASIL injections, and her chest pressure and the achiness in her neck are subsiding. It is unknown if her blood pressure remained elevated. Additional information is not expected.

Other Meds: None

Lab Data: Unknown

History: Penicillin allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **349322-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Oct-2007	01-Nov-2007	30	15-Jun-2009	15-Jul-2009	--	WAES0905USA02843	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adrenal insufficiency

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female who was vaccinated with the first dose of GARDASIL on 02-Aug-2007, second dose on 02-Oct-2007, and third dose on 20-Mar-2008. The patient did not receive any concomitant vaccinations when the GARDASIL vaccinations were administered. In approximately November 2007, the patient began to have signs and symptoms of Adrenal Insufficiency. The patient had sought medical attention. At the time of reporting, the outcome of adrenal insufficiency was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Serum stimulated, 04/??/09, Adrenal Insufficiency.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 349323-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Jan-2009	14-Jan-2009	5	15-Jun-2009	15-Jul-2009	OK	WAES0905USA02892	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Convulsion, Cough, Cryotherapy, Distractibility, Dizziness, Feeling hot, Headache, Hyperhidrosis, Hypersomnia, Hypotonia, Loss of consciousness, Menorrhagia, Myoclonus, Nasal congestion, Otitis media, Pallor, Pelvic pain, Pyrexia, Road traffic accident, Sinus headache, Skin papilloma, Staring, Syncope, Upper respiratory tract infection, Vomiting, Weight increased

Symptom Text: Information has been received from a physician Assistant and a Licensed Practical Nurse concerning a 16 and half years old female with familial risk factor who was vaccinated with three doses of GARDASIL ON 11-APR-2008, 13-JUN-2008 and 9-JAN-2009. Concomitant therapy included ALASE. The patient had no known drug allergies. On 25-AUG-2008 the patient experienced syncope and was sent to the emergency room (hospital name unknown). At the patient's office visit on 16-JAN-2009 it was reported that on 14-JAN-2009 the patient felt dizzy while driving (with a sibling as passenger), she pulled over then blacked out. On 16-JAN-2009 the patient had CT scan and EEG done and CT scan results were normal but EEG results were abnormal and it showed that she underlying predisposition for seizures. It was known that the patient had a "family history of seizure disorder". The patient was referred to Neurologist. The neurologist did not wish to provide any information on this case. A nurse at the county health department reported that the patient was not in their system. Therefore, lot #'s could not be provided. The patient's experience was not felt to be life-threatening. The patient's status was listed as recovering. The health care professionals contacted during telephone follow up could not supply the following information: lot numbers and hospital name (ER visited 25-AUG-2008). No further information is available at this time. 6/23/09 Neurological consult received DOS 4/02/09. Assessment: seizures, syncope. Patient c/o of an episode consisting of stomach hurting, sweating, feeling hot. Pale and unable to recall subsequent events. Lost conciousness. Also slumped over once while driving and had car wreck. Lightheadedness. Episodes of staring. Myoclonic jerks while sleeping. Sleeps a lot, recent weight gain, distractible. ICD-9 Codes: Spells 780.39, Abnormal EEG 794.02, Syncope 780.2, R/O Epilepsy 345.90 6/29/09 Medical records received DOS 8/07/08 to 4/08/09 Assessment: Cephalgia and Syncope. Patient presents with abd

Other Meds: ALASE

Lab Data: computed axial, 01/16/09 - normal; electroencephalography, 01/16/09 - abnormal; underlying predisposition for seizure 6/23/09 Medical records received LABS and DIAGNOSTICS: EEG - single generalized burst of spike wave activity. Plts 457

History: 6/23/09 Medical records received PMH: Tonsillectomy and adenoidectomy.

Prex Illness: Familial risk factor; Contraception

Prex Vax Illns:

Vaers Id: **349324-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	07-Aug-2007	Unknown		15-Jun-2009	29-Jun-2009	PA	WAES0905USA02921	25-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0171U	1	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Cellulitis, Drug toxicity, Eczema, Fatigue, Hyperhidrosis, Infection, Iron deficiency, Lymphadenopathy, Lymphomatoid papulosis, Mouth ulceration, Nausea, Oral contraception, Pneumonitis, Pruritus, Rash erythematous, Rash generalised, Rash papular, Rash pustular, Scar, Skin nodule, Skin ulcer, Urticaria, Weight decreased

Symptom Text: Information has been received from a physician concerning a female who was born on 09-Jun-1988 was vaccinated the first dose of GARDASIL (Merck) (LOT # 0210U), 0.5ml, on 23-MAY-2007. On 07-AUG-2007 she got the second dose of GARDASIL (LOT # 655620/0171U). There were no concomitant medications. Subsequently the patient experienced lymphomatoid papulosis after getting the first dose and second dose of GARDASIL. After that the patient sought medical attention. The patient never received the third dose. At the time of the report, the outcome was unknown. A medical assistant reported the patient's mother advised that the patient was undergoing treatment (no further information given) and would not be receiving the third dose. Additional information has been requested. 6/25/09 Medical records received DOS 12/28/07 to 12/24/08. Assessment: Lymphoid papulosis and iron deficiency. Patient presented with hives on upper extremities. Acne on face. Cellulitis L thigh, lymphadenopathy in groin. Lymphoid papulosis lesions on face, eyelid, legs buttocks. Shotty adenopathy neck. Infection R thigh. Oral contraceptives. Vaccine record: HPV-1 Merck 0210U RA 22.Nov.09 6/29/09 Medical records received 12/28/07 to 12/24/08. Additional information abstracted: Patient presented to oncology center with sweats at night, weight loss, rash and itching. Multiple open weeping papules yellowish in nature, others erythematous and reddish/brown, some are papulopustular. Present on eyelids, neck, arms, back, and posterior portion of legs. 8/24/09 Dermatology consult received. FINAL DX: lymphomatoid papulosis, type C, leaving scars. Records reveal patient experienced widespread & painful nodular lesions, ulcer on left hand, intermittent mouth sores, fatigue, nausea. Tx w/methotrexate starting 6/08, clobetasol propionate cream & folic acid. Developed MTX-induced pneumonitis. MTX d/c'd. Punch biopsy done when developed scaly patches c/w eczematous dermatitis. Tx w/PUVA & Oxsoralen starting 12/08 w/good results.

Other Meds: None

Lab Data: None. 6/25/09 Medical records received DOS 12/28/09 to 12/24/08. LABS and DIAGNOSTICS: Chest X-ray negative for lymphoma. PET CT scan negative for lymphoma. Blood work normal. Bone marrow - low ferritin.

History: None. 6/25/09 Medical records received DOS 12/28/09 to 12/24/08. Surgery for wrist fracture.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349325-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jul-2008	24-Jul-2008	0	15-Jun-2009	15-Jul-2009	--	WAES0905USA02951	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Skin papilloma

Symptom Text: Information has been received from a Nurse Practitioner concerning a 17-year-old female patient who on 07-AUG-2007 was vaccinated with the first dose of GARDASIL 0.5ml. On 24-JUL-2008 the patient was vaccinated with the second dose of GARDASIL 0.5ml. Two to four weeks after the second after the second dose, the patient experienced developing "hundreds of warts" on her arms legs. Approximately 6 months later the patient recovered. The patient didn't seek medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349326-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Apr-2009	08-Apr-2009	0	15-Jun-2009	15-Jul-2009	PA	WAES0905USA03183	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Unknown	Subcutaneously	
	VARCEL	MERCK & CO. INC.	0792X	1	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site inflammation, Injection site swelling

Symptom Text: Information has been received from a physician concerning an 11 year old female with no illness at time of vaccination or pre-existing, birth defects or medical conditions who on 08-Apr-2009 at 9:00, was vaccinated SQ with the third dose of GARDASIL (lot# 661952/1129X) into her right deltoid. Concomitant vaccine received at the same date included the second dose of VARIVAX (lot #:660566/0792X via SQ into her left deltoid. On 10-Apr-2009 at 09:30, the patient experienced right deltoid red swollen and inflamed to 4 inches wide. The patient was seen by a physician. No relevant lab tests was performed. Subsequently, 7 days after onset, the patient recovered. No information is available.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349327-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	IL	WAES0905USA03218	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Information has been received from a licensed practical nurse concerning a female who was vaccinated with a dose of GARDASIL. Subsequently, the patient developed swollen lymph nodes after one vaccination with GARDASIL. Nodes haven been swollen for more than one week. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349328-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	08-Apr-2008	08-May-2009	395	15-Jun-2009	15-Jul-2009	NV	WAES0905USA03240	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 20 years old female who was vaccinated with GARDASIL three times: 1st dose given on 25-Sep-2007 (Lot# 65439/0742U), 2nd dose given on 27-Nov-2007 (Lot# 655322/1211U), 3rd dose given on 08-Apr-2008 (Lot# 0151X). No other vaccine administered. Concomitant therapy included ORTHO TRI-CYCLEN. On 08-May-2009 the patient had a Pap test done which come back abnormal. The physician reported that the result of the patient's test was that she had a high risk of GARDASIL, but the specific type of GARDASIL had not been determined. The status of the patient was unknown at the report time, and the patient had been outside the country. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: Pap test, the specific type of HPV has not been determined

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349329-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-May-2009	18-May-2009	0	15-Jun-2009	15-Jul-2009	CA	WAES0905USA03248	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1605X		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Syncope

Symptom Text: Information has been received from representative reported experience as reported by a nurse concerning a female patient who on 18-MAY-2009 was vaccinated with the first dose of GARDASIL (Lot # 661953/1130X), 0.5ml. After receiving the patient fainted. The outcome was unknown. The patient sought medical attention. Later on 27-MAY-2009, C.M.A. provided the following details: a female patient with past history of fainting with blood draw who on 18-MAY-2009 was vaccinated with the first dose of GARDASIL (Lot # 661953/1130X), 0.5ml in the right arm after receiving VAQTA (Lot#663490/1605X) in the left arm. Concomitant therapy is YAZ. After receiving the first dose of GARDASIL (Lot # 661953/1130X) , the patient fainted. When she came to, her B/P was 115/68, she was given something to eat and drink and then fully recovered. Additional information has been requested.

Other Meds: YAZ

Lab Data: blood pressure, 05/18/09, 115/68

History: Syncope

Prex Illness:

Prex Vax Illns:

Vaers Id: **349330-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0905USA03257	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with a first dose of GARDASIL. Subsequently the patient experienced arm pain during her first injection. The patient present status was unknown at the report time. A call received from the nurse mentioned that she did not remember which patient experienced pain following GARDASIL vaccination as this incident occurred several months ago. She would try to go back through patient records and identify the patient. If she can find the patient, she will call back with specific details including patient name, date of birth, vaccination dates/lot numbers, AE onset date, patient outcome and / or status, etc. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349331-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	01-May-2009		15-Jun-2009	15-Jul-2009	OR	WAES0905USA03276	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from an office manager concerning a 15 year old female who on 11-NOV-2008 was vaccinated with the first dose of GARDASIL (Lot#661764/0650X), 0.5ml , IM and the second dose(Lot# 661841/0653X) 0.5ml, IM on 10-FEB-2009. The patient had been losing her hair after the third dose of GARDASIL (Lot#662300/0100Y), 0.5ml, IM in her right arm on 11-MAY-2009. Concomitant therapy included DEPO-PROVERA, 150mg, IM in the left arm. Caller was requesting a lot check of this vaccine due to the patient having adverse experience. The patient had sought medical attention. The outcome was unknown. The Lot Check had been initiated. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349332-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	NY	WAES0905USA03359	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a Registered Nurse (R.N) concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (Lot # not reported). It was reported that on an unspecified date the patient fainted after getting the vaccine. The patient sought unspecified medical attention. The outcome of the patient was unknown. Follow up information was received from a Registered Nurse (R.N) who confirmed that there was no patient information to report. It was reported that the Registered Nurse was not aware of any patient who fainted. It was reported that she will not be supplying any patient information as she had no knowledge of any specific patient fainting in her practice following vaccination with GARDASIL. Attempts to verify the existence of an identifiable patient have been unsuccessful.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349333-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	10-Mar-2009	11-Mar-2009	1	15-Jun-2009	15-Jul-2009	FL	WAES0905USA03367	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0074Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a medical assistant concerning a 23 year old female with not reported drug reactions/allergies and medical history, who on 10-MAR-2009 was vaccinated IM with 0.5 ml first dose of GARDASIL (lot number: 0074Y). There was no concomitant medication. The medical assistant reported that the patient developed hives on her shoulder and back, after receiving her first and only dose of the GARDASIL vaccine. The patient was recovered "3 days after vaccination" (13-MAR-2009). The patient did not seek medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349334-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	CT	WAES0905USA03371	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a teenage female who within the last two years (approximately 2007) was vaccinated IM with a dose of GARDASIL (route in the series and lot number unspecified). The physician reported that the patient "fainted" after getting the vaccine. The outcome of patient was recovered. The patient sought unspecified medical attention. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349335-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-May-2009	20-May-2009	7	15-Jun-2009	15-Jul-2009	FL	WAES0905USA03380	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Oedema peripheral

Symptom Text: Information has been received from a certified medical assistant concerning a 12 year old female patient with cystic fibrosis, no drug reactions/allergies, who on 13-MAY-2009 was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (Lot # 661531/1311X). On 20-MAY-2009, the patient's arm became so swollen after receiving her first and only dose of GARDASIL that she could not lift her arm. The patient sought unspecified medical attention. There were no laboratory or diagnostic tests performed. At the time of reporting, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Cystic fibrosis

Prex Vax Illns:

Vaers Id: **349336-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
34.0	F	21-May-2009	21-May-2009	0	15-Jun-2009	15-Jul-2009	--	WAES0905USA03385	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1702X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaccination site pain, Wrong drug administered

Symptom Text: Information has been received from a 34 year old patient registered nurse with allergies to IMITREX, COMPAZINE, MACROBID, for the Pregnancy Registry for GARDASIL. The patient stated that on 21-MAY-2009 she was supposed to receive RHOGAM and inadvertently received a first dose of GARDASIL (lot # 1702X). The vaccination was painful. Concomitant medications on the same day included RHOGAM. The nurse stated that the error was immediately recognized that the patient receive GARDASIL instead of RHOGAM, it was a medication error and not product confusion. At the time of reporting, 29 weeks gestation and the pregnancy was normal. Her last menstrual period was 31-OCT-2008 and her EDD was 07-AUG-2009. A follow-up appointment was scheduled with the physician. Additional information has been requested.

Other Meds: RHOGAM

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 10/31/2008); Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **349337-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2008	Unknown		15-Jun-2009	15-Jul-2009	CT	WAES0905USA03402	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN		Unknown	Unknown	
	TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Demyelination, Hypoaesthesia

Symptom Text: Information has been received from a physician concerning a teenage female who within the last year was vaccinated with a dose of GARDASIL vaccine. Concomitant therapy included tetanus toxoid (manufacturer unspecified). Two to three months later the patient she had symptoms of numbness and after MRI demyelinating lesions were discovered. Additional information is not expected.

Other Meds:

Lab Data: Magnetic resonance, demyelinating lesions

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349338-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Apr-2009	21-Apr-2009	0	15-Jun-2009	15-Jul-2009	--	WAES0905USA03625	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Menstrual disorder

Symptom Text: Information has been received from a consumer for the pregnancy registry for GARDASIL concerning his 17 year old girlfriend with anemia, irregular menstrual cycle and no known drug allergies/ drug reactions who on 21-Apr-2009 was vaccinated with the first 0.5ml dose of GARDASIL (lot# not reported). There was no concomitant medication reported. It was reported that about two to three weeks after getting the vaccine (approximately on 06-May-2009), the patient went to a clinic and had a urine pregnancy test done, which showed she was pregnant. It was reported that the last menstrual period was on 27-Mar-2009. It was reported that on 18-May-2009 the patient had her menstrual cycle. It was reported that the patient has not seen a physician since received her menstrual cycle on 18-May-2009. It was reported that the consumer was uncertain if his girlfriend was still pregnant or not as she had not seen a physician since the menstrual cycle on 18-May-2009. The estimated delivery date was on 01-Jan-2010. No further information is available.

Other Meds: None

Lab Data: Urine beta human, 05/05/2009, showed she was pregnant.

History:

Prex Illness: Pregnancy Nos (LMP= 3/27/2009) Anaemia; Irregular menstrual cycle

Prex Vax Illns:

Vaers Id: **349340-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
30.0	F	10-Apr-2007	Unknown		17-Jun-2009	18-Jun-2009	FR	WAES0906USA01694	26-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0859F	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Allergy to animal, Allergy to plants, Asthma, Condition aggravated, Dyspnoea, Eye pruritus, Fatigue, Food allergy, Headache, House dust allergy, Malaise, Milk allergy, Mycotic allergy, Ocular hyperaemia, Pyrexia, Rash pruritic, Respiratory tract inflammation, Seasonal allergy, Sneezing, Urticaria

Symptom Text: Initial case was reported on 02-JUN-2009 by a patient and additional information from healthcare professional was received on 04-JUN-2009 concerning a 30 year old woman who was vaccinated with the first, second and third dose of GARDASIL on 10-APR-2007 (lot#654740/0859F, batch# NE37970), 20-JUN-2007 (lot#655376/0572F, batch#NE47370) and 10-OCT-2007 (lot#655376/0572F, batch#NE47370). On an unspecified date sometime after vaccination with dose one in 2007 the patient experienced itching eyes, sneezing and tiredness. These symptoms aggravated on unspecified date following vaccination with the second dose. Now the patient reacted to her pets, got headache, and experienced red eyes constantly and a general malaise (unspecified date in 2007). After the third dose of vaccine the patient developed dyspnea that aggravated with time (unspecified date). The patient visited the hospital and was diagnosed with allergy to mugwort, dog, mite and mold (unspecified date). No pharmaceutical treatment was taken for the condition since the patient was skeptical towards drugs considering her medical history (a lot of side effects, please see below). In February/March 2008 the patient developed a terribly itching rash covering the entire front side of her body, from neck to feet. The doctor could not diagnose the patient, however suspected psoriasis, and prescribed weak steroids and sleeping pills. The symptoms persisted and the patient also developed a constant fever (unspecified date in 2008). After another visit to another doctor the patient was prescribed stronger steroids that made the symptoms go away. Another doctor later diagnosed the itchy rash as urticaria. As the dyspnea aggravated the patient saw a new doctor and was examined with lung x-ray to rule out angioedema (unspecified date in 2008). The results came out normal. BRICANYL for the dyspnea and corticosteroids (manufacturer unknown) for the urticaria (in case of recurrence) was prescribed. 1-2 weeks after the hospital visit the patient woke up in the middle of night wi

Other Meds: Unknown

Lab Data: X-ray, normal, ??08; Allergy test, test for mugwort, pollen, dog, fur animals, mite, milk protein and mold were positive

History: Urticaria; Premenstrual syndrome.

Prex Illness: Asthma; Drug hypersensitivity; Cold; Drug side effect; Blister; Eczema.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349341-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		17-Jun-2009	18-Jun-2009	FR	WAES0906USA02004	18-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diabetes mellitus, Idiopathic thrombocytopenic purpura, Vulvovaginal human papilloma virus infection

Symptom Text: Case received from a specialist in hospital on 04-JUN-2009 and transmitted via a sales representative. A 16 year old female patient experienced idiopathic thrombocytopenic purpura (ITP) after she received the third dose of GARDASIL (batch number not reported) on an unspecified date. Two months after vaccination, the patient presented with ITP with platelets at 10000. She was treated with corticosteroids (unspecified) but experienced a significant diabetic decompensation. Afterwards she presented with vulvar condylomatosis. At the time of reporting for typing was oncogene, HPV 16 was detected. To be specified that before the administration of the first dose of GARDASIL, the patient was sexually active and her platelets count was 110000. According to the gynecologist, condylomata were related to sexual relationships prior to vaccination and for the hematologist, ITP was not related to vaccination. Both specialists ie gynecologist and hematologist considered that vaccination could have been a trigger factor. Idiopathic thrombocytopenic purpura, diabetes steroid-induced, vulvovaginal condyloma and pap smear abnormal were considered to be other important medical events by the specialist. Other company numbers included E2009-04812. No further information is available.

Other Meds:

Lab Data: Pap test, abnormal; platelet count, 10000 cu/ml; platelet count, 110000 cu/ml

History:

Prex Illness: Low platelets; Sexually active

Prex Vax Illns:

Vaers Id: **349366-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	RI	WAES0905USA03635	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menorrhagia

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who "a couple of months ago" was vaccinated with the first and second dose of GARDASIL vaccine (Lot # not reported). It was reported that the patient experienced heavier menstrual cycle after receiving the first and second dose of GARDASIL vaccine. The patient was seen by the physician. The outcome of the patient was unknown. It was reported that the therapy with GARDASIL was discontinued on an unspecified date. Additional information has been required.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349367-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	12-May-2009	19-May-2009	7	15-Jun-2009	15-Jul-2009	CA	WAES0905USA03670	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Haemorrhage, Pruritus, Rash

Symptom Text: Information has been received from a physician concerning a 25 year old female with a history of miscarriage before the vaccination who on 12-MAY-2009 was vaccinated with the first dose of GARDASIL (LOT # 0294Y, 0.5ml, intramuscular administration). There was no concomitant medication. The patient developed rash on her both arms and legs one week after the vaccination. The patient called the office and described the rash as itchy and "bursting" blood vessels. At the time of reporting the patient was recovering. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Miscarriage

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349368-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-May-2009	19-May-2009	0	15-Jun-2009	15-Jul-2009	CA	WAES0905USA03677	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Tachycardia

Symptom Text: Information has been received from a physician concerning an 11 year old female who on 19-MAY-2009 was vaccinated with the second dose of GARDASIL (LOT# 661841/0653X, route and site of administration not reported). The patient experienced dizziness after getting the second dose of GARDASIL and about 4 to 7 hours later she became tachycardia up to 150 that stayed for 2 or 3 days. She received the first dose of GARDASIL (LOT#, route and site of administration not reported 0.5ml) on 19-MAR-2009 with no adverse event. The outcome of dizziness was unknown. Follow up information has been received on 29-MAY-2009. It was reported by the office manager that on 19-MAR-2009 the patient received the first dose of GARDASIL (lot#661952/1129X), VAQTA (lot#662532/1584X), ADACEL (lot#UF452AA) and MENACTRA (lot#42870AT). On 19-MAY-2009 the patient went to the Emergency Room for some unspecified medical attention. In additional follow up the responsible physician stated that the patient was not admitted to the hospital. The patient's EKG revealed Sinus Tachycardia, heart rate 140 to 150. The tachycardia lasted for one day. The patient's dizziness and tachycardia resolved. The patient was referred to cardiologist. The patient had an appointment at the vaccinating physician's office on 26-MAY-2009 and the patient was completely normal. It was reported that the patient was scheduled for the third dose of GARDASIL in 3 and a half months. No further information is available. The patient was treated in the emergency room at hospital.

Other Meds:

Lab Data: electrocardiogram, 05/19/09, sinus tachycardia, HR 140 to 150

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349369-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Mar-2008	31-Mar-2008	0	15-Jun-2009	15-Jul-2009	MN	WAES0905USA03692	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a mother concerning her daughter who on 31-MAR-2008 was vaccinated with first dose of GARDASIL (Lot # 659180/1758U). Concomitant therapy included a dose of VARIVAX (Lot # 658287/1173U) (MSD) on 31-MAR-2008 and Acne cream. Subsequently the patient began to lose hair after her first vaccination. The patient was vaccinated with the other doses of GARDASIL as follows: 2nd dose (Lot # 656371/0181U) on 24-OCT-2008, and 3rd dose (Lot # 661953/1130X) on 21-MAY-2009. Other concomitant therapy included influenza virus vaccine (unspecified) on 24-Oct-2008. The patient didn't seek medical attention. At the report time, the patient was not recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 349370-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	03-Mar-2008		15-Jun-2009	15-Jul-2009	--	WAES0905USA03695	24-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a nurse practitioner for GARDASIL, a Pregnancy Registry product, concerning a 23 year old female with allergies to sulfa, MACROBID and a medical history of Attention Deficit Disorder, depression, anxiety and obesity who on unspecified date was vaccinated with the 1st and 2nd dose of GARDASIL. Concomitant therapy included EFFEXOR and NECON 1/35. The doses were administered at a different facility so the nurse practitioner did not have specific dates or lot numbers. The nurse practitioner stated that the patient did not document if she received any concomitant vaccines when she received the GARDASIL. Subsequently, after two doses of GARDASIL, the patient became pregnant. Unspecified medical attention had been sought. The patient delivered her baby at 33 weeks on 20-Oct-2008. The patient told the nurse practitioner that the baby was "doing great". Dose 3 has not been administered yet. Dose 3 was due in April 2008 but was never administered. At the time of reporting, the patient status was "fine". Additional information has been requested.

Other Meds: NECON 1/35, EFFEXOR

Lab Data: Unknown

History: Attention deficit disorder; Depression; Anxiety; Obesity

Prex Illness: Pregnancy NOS (LMP = 3/2/2008) Sulfonamide allergy; Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **349371-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Feb-2009	25-Feb-2009	0	15-Jun-2009	15-Jul-2009	OH	WAES0905USA03777	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3031AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Myalgia, No reaction on previous exposure to drug, Urticaria

Symptom Text: Information has been received from a physician concerning a 15 year old female student with no medical history and no known drug allergy who on 25-FEB-2009 at 13:45 was vaccinated with the first dose of GARDASIL IM into her left deltoid (lot # 660612/0229X). On the same day at 13:45, the patient also received the first dose of ADACEL IM into her right deltoid (lot # C3031AA). There was no illness at the time of vaccination. On 26-FEB-2009 the patient's mother stated that the patient went to bad awake with sore muscles and headache after vaccines. The patient was given ibuprofen and the adverse events had relief. On 30-APR-2009, the patient returned for the second dose and her mother noted that she forgot to mention that the patient had hives on arms and chest after vaccines. The physician advised against the second injection. The patient had had prior ADACEL without reaction. At the time of reporting, the outcome was unknown. The patient did not seek medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349372-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-May-2009	27-May-2009	26	15-Jun-2009	15-Jul-2009	GA	WAES0905USA03812	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site mass, Injection site pain

Symptom Text: Information has been received from a Certified Medical Assistant (C.M.A.) concerning a 24 year old female patient who on 13-MAR-2009 was vaccinated with the first dose of GARDASIL vaccine (Lot # 661846/1312X) with no incident. On 01-MAY-2009 the patient received the second dose of GARDASIL vaccine (Lot # 658271/0558X). There was no concomitant medication reported. It was reported that "26 days after receiving vaccine", on 27-MAY-2009, the patient developed a red bump at the injection site after receiving GARDASIL vaccine. On 27-MAY-2009 the patient called to the office to report that she has developed a "bump" under the skin at the injection site was painful to the touch. There were no laboratory diagnostic tests performed. The patient has not been seen by the physician for evaluation but was offered a physician's appointment and the patient stated that "she would call back to schedule and appointment to see the physician if the bump under skin at the injection site and the pain to touch persisted". It was reported that the patient had not recovered at the time of the report. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349373-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Oct-2008	01-Oct-2008	0	15-Jun-2009	15-Jul-2009	--	WAES0905USA03847	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Brachial plexus injury, Condition aggravated, Laboratory test, Nuclear magnetic resonance imaging, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning his 16 year old daughter with "brachial plexus" of her right arm which was diagnosed a few years ago, and allergy to viral medications (it caused brachial plexus) who on 01-OCT-2008, 02-DEC-2008 and on 21-APR-2009 was vaccinated with the first, second and third doses (o.5 ml) of GARDASIL (Lot # not reported) respectively. Concomitant medication included "pain medication" (unspecified). It was reported that "after first dose" of GARDASIL the nerve damage on her right arm "flared up". After receiving her second dose of GARDASIL the nerve damage (brachial plexus) occurred on her left arm. It was reported that after receiving her third dose of GARDASIL the nerve pain (brachial plexus) "flare up" on her right arm again. The patient sought unspecified medical attention. There were "numerous laboratory work, MRI" performed (results not provided). It was reported that the patient was recovering at the time of the report. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Brachial plexus lesion; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **349374-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	15-May-2009	16-May-2009	1	15-Jun-2009	15-Jul-2009	IN	WAES0905USA03861	24-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Influenza like illness, Injection site pain, Pain in extremity

Symptom Text: Information has been received from a Registered Nurse concerning a 25 year old female patient with no pertinent medical history and no drug reactions or allergies who on 15-MAY-2009 was vaccinated with a first dose of GARDASIL (Lot # 658271/0558X) 0.5ml intramuscularly in the upper left arm. Concomitant therapy included SEASONALE. On 16-MAY-2009 the patient experienced severe arm pain and soreness from the injection site and down the arm. There was slight numbness. On 15-MAY-2009 pregnancy test was performed and was negative. On 19-MAY-2009 the patient went to the emergency room for flu like symptoms and the arm pain. She was given TORADOL for pain. On 20-MAY-2009 the patient recovered. Follow up information from a certified medical assistant revealed that the patient received no other vaccines at the time of the GARDASIL. The patient went to the Urgent Care Center on 19-MAY-2009. Charts showed EKG and lab work done there were normal. Additional information is not expected.

Other Meds: SEASONALE

Lab Data: electrocardiogram, 05/19/09 - normal, diagnostic laboratory, 05/19/09 - lab work: normal; beta-human chorionic, 05/15/09 - negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349375-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	NY	WAES0905USA03862	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Helicobacter infection

Symptom Text: Information has been received from a physician concerning a "14 year" old female patient who was hospitalized couple days for "Helicobacter pylori". On unspecified day she received second dose of GARDASIL (Lot # not reported). Concomitant therapy included VARIVAX and NEXIUM. After got the vaccine the patient felt like fainting. The patient sought unspecified medical attention. At the time of the report on 27-MAY-2009 the patient had recovered. Additional information has been requested.

Other Meds: NEXIUM

Lab Data: Unknown

History: Hospitalisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **349376-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-May-2009	21-May-2009	0	15-Jun-2009	15-Jul-2009	FL	WAES0905USA03865	11-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Injection site pain, Nausea, Vomiting

Symptom Text: Information has been received from an emergency medical technician concerning a 15 year old female patient with no drug reactions or allergies who on approximately 20-MAY-2009 had a yeast infection. On 21-MAY-2009 she received a dose of GARDASIL (lot # not reported) intramuscularly. Concomitant therapy included SERTRALINE HC1. On 21-MAY-2009 the patient developed nausea, headache and vomiting. The patient also complained of soreness at site of injection. At the time of the report on 27-MAY-2009 the patient had not recovered. The patient sought medical attention called the office. There were no laboratories diagnostics performed. Additional information has been requested. 6/22/09 Medical records received DOS 5/12/09 to 6/3/09. Patient presents with soreness at injection site, headaches, nausea and vomiting. At time of immunization was being treated with Diflucan for candidiasis of vulva and vagina.

Other Meds: sertraline hydrochloride

Lab Data: None Medical records received 6/22/09 LABS and DIAGNOSTICS: STD Screen (-).

History: Medical records received 6/22/09 PMH: Anxiety Disorder Generalized, Obsessive-compulsive disorders, candidiasis, dysmenorrhea.

Prex Illness: Yeast infection

Prex Vax Illns:

Vaers Id: **349377-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	CT	WAES0905USA03883	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Optic neuritis

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL. One or two months after the GARDASIL dose the patient experienced optic neuritis. This is one of two reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349378-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	22-May-2009		15-Jun-2009	15-Jul-2009	LA	WAES0905USA03904	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site pain, Vaccine positive rechallenge, Vision blurred

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine. On 22-MAY-2009, the patient was vaccinated with the second dose of GARDASIL vaccine. After receiving the first dose, the patient experienced pain at the injection site and then was fine. After receiving the second dose, the patient experienced arm pain at the injection site which went up her arm and started to have pain in her head and then when she looked to that side of the head her vision was blurry. The patient called the physician and the physician told the patient "if the symptoms were still occurring or get worse she should call the office back". At the time of reporting, the patient had not recovered. Additional information has been requested. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349379-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	20-May-2009	26-May-2009	6	15-Jun-2009	15-Jul-2009	SC	WAES0905USA03905	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Pain in extremity

Symptom Text: Information has been received from a nurse concerning a 23 year old female patient who on 20-MAY-2009 was vaccinated with a second dose of GARDASIL (Lot # 0294Y). On 26-MAY-2009 she could hardly move her arm due to pain. On 27-MAY-2009 the patient went to the physician and he stated there was no cellulitis. At the time on the report on 27-MAY-2009 the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349380-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Dec-2008	29-Dec-2008	0	15-Jun-2009	15-Jul-2009	--	WAES0905USA03906	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Injection site pain

Symptom Text: Information has been received from a consumer, for the Pregnancy Registry for GARDASIL, concerning her 15 year old daughter with seasonal allergy who on 22-OCT-2008, on 29-DEC-2008 and on 22-APR-2009 was vaccinated with a first, second and third dose respectively, of GARDASIL (routes and lot numbers not reported). Concomitant medication were unspecified. The mother reported that on 1-MAY-2009, the patient conducted a home urine pregnancy test and it came up positive. The patient went to see her physician and the physician conducted a urine pregnancy test and the result came back positive again (LMP: 26-MAR-2009, EDD: 31-DEC-2009). The mother added the patient mentioned that after receiving the second and third dose of GARDASIL, the patient experienced soreness on the injection sight. Also the mother reported the patient is fine now. The patient sought medical attention at the physician's office. No further information provide. Additional information has been requested.

Other Meds: Unknown

Lab Data: urinalysis, 05/01/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = 3/26/2009); Seasonal allergy

Prex Vax Illns:

Vaers Id: **349381-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0905USA04039	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nervousness, Syncope

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a female who on 27-MAY-2009 was vaccinated with a dose of GARDASIL (LOT# not reported). It was unknown which dose in the series the patient received. On 27-MAY-2009, since vaccination, the patient fainted after receiving the vaccination. The nurse did not think the fainting was related to the vaccine and stated, "thought the patient was nervous and skittish about shots". It was reported that the patient sought medical attention in the office. The patient's outcome was unknown. Follow-up information has been received from via a phone call from the registered nurse (R.N.) concerning a female who on months ago was vaccinated with the first dose of GARDASIL (LOT# not reported). The registered nurse said the patient was fine. The mother reported that the patient usually dose this when she gives blood or gets shots. The registered nurse (R.N.) contacted during telephone follow-up could not supply the following information: patient name, date of birth, lot number, date of event and recovery status. No further information is available at this time.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Nervousness

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349382-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	VA	WAES0905USA04056	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from another physician (not the patient's physician) concerning a female who was vaccinated with a dose of GARDASIL (Lot # was not available). The patient experienced a "rash like bumps after receiving GARDASIL". The patient was seen by the physician to seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349383-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0906USA00009	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Orthostatic hypotension

Symptom Text: Information has been received from a physician concerning four female patients who were vaccinated with doses of GARDASIL vaccine. Subsequently the patients experienced postural hypotension. Unspecified medical attention was sought. At the time of this report, the outcomes were unknown. Follow up information was received from a physician on 26-MAY-2009. The patient was the nurse's daughter. The physician stated that after further discussions, it was decided that there was no relation to these events and the GARDASIL vaccination. The physician was confident that the patient was fine. This is one of several cases from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349384-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0906USA00010	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Orthostatic hypotension

Symptom Text: Information has been received from a physician concerning four female patients who were vaccinated with doses of GARDASIL. Subsequently the patients experienced postural hypotension. Unspecified medical attention was sought. At the time of this report, the outcomes were unknown. Follow up information was received from a physician on 26-MAY-2009. The patient was the pharmacist's daughter. The physician stated that after further discussions, it was decided that there was no relation to these events and the GARDASIL vaccination. The physician was confident that the patient was fine. This is one of several cases from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349385-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0906USA00011	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Orthostatic hypotension

Symptom Text: Information has been received from a physician concerning four female patients who were vaccinated with doses of GARDASIL. Subsequently the patients experienced postural hypotension. Unspecified medical attention was sought. At the time of this report, the outcomes were unknown. Follow up information was received from a physician concerning a female patient. The physician stated that after further discussions, it was decided that there was no relation to these events and the GARDASIL vaccination. The physician was confident that the patient was fine. This is one of several cases from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349386-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0906USA00103	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Immediate post-injection reaction, Myalgia

Symptom Text: Information has been received from a nurse through a representative concerning a female patient who was vaccinated with the first dose of GARDASIL. Subsequently the patient experienced immediate reactions including chills and muscle pain, The muscle pain lasted for about 2 weeks. It was unknown if the patient sought medical attention. At the time of report the patient recovered from chills and muscle pain. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349387-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	15-Jul-2009	--	WAES0906USA00112	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a medical assistant concerning a female patient who was vaccinated with the first dose of GARDASIL and had fainted. Unspecified medical attention had been sought. The patient recovered. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349388-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-May-2009	28-May-2009	9	15-Jun-2009	15-Jul-2009	--	WAES0906USA00118	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local swelling

Symptom Text: Information has been received from a nurse practitioner concerning a 11 year old female who on 19-MAY-2009 was vaccinated with her first dose of GARDASIL (Lot#661841/0653X). The concomitant medication was not reported. On 28-MAY-2009 the patient noticed after showering that her neck was swollen. It just suddenly popped up on the clavicular region within an hour's time frame. it was unknown whether the patient sought medical attention. The outcome was unknown at the report time. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349389-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Jun-2009	14-Jul-2009	--	WAES0906USA00135	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning a patient who on an unspecified date was vaccinated with a dose of GARDASIL (LOT# not reported). Subsequently the patient experienced injection site pain. The physician did not see the patient himself and he heard this through a pediatric colleague. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349390-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-May-2008	29-May-2008	0	15-Jun-2009	14-Jul-2009	--	WAES0906USA00139	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a Nurse Practitioner concerning a female about 14 years old who was vaccinated with the first 0.5 mL dose of GARDASIL on approximately 29-MAY-2008. the patient experienced hives all over her body within 24 hours of receiving her first dose of GARDASIL. The patient was recovered after taking BENADRYL. No lot number was provided. Therapy with GARDASIL was discontinued. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349391-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-May-2009	Unknown		15-Jun-2009	14-Jul-2009	NY	WAES0906USA00143	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Influenza like illness

Symptom Text: information has been received from a physician concerning an approximately 25 year old female who on "20-MAY-2009" was vaccinated, 0.5 ml, with the first dose of GARDASIL (route and lot number were not provided). Subsequently, the patient experienced flu like symptoms. The patient went to the emergency room for treatment however it was unknown if she was admitted into the hospital. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349392-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	14-Jul-2009	--	WAES0906USA00242	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a medical assistant concerning a female patient who was vaccinated with the first dose of GARDASIL and had fainted. Unspecified medical attention had been sought. The patient had recovered. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349393-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jun-2009	14-Jul-2009	--	WAES0906USA00243	14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a medical assistant concerning a female patient who was vaccinated with the first dose of GARDASIL and fainted. Unspecified medical attention has been sought. The patient had recovered. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349405-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	28-Aug-2008	31-Aug-2008	3	17-Jun-2009	18-Jun-2009	NJ		28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Anterior interosseous syndrome, Hypokinesia, Limb discomfort, Motor dysfunction, Muscular weakness, Pain in extremity, Radiculitis brachial

Symptom Text: Dianosis: Left brachial neuritis after HPV/Gardasil vaccinations..History of Illness: 1/20/2009 - Presented for initial evaluation by hand surgeon. By history, patient noticed that her entire left arm was painful 3-4 days after vaccination (Gardasil vac. #2.) Arm pain lasted 24 - 48 hours, then the patient noticed inability to flex the tip of her left thumb. 2/06/2009 - EMG remarkable for left anterior interosseous nerve syndrome. 2/10/2009 - Patient has no active FPL function and complains of loss of dexterity on the left. 3/10/2009 - No active flexion of her left thumb IP joint. 5/19/2009 - Plan to continue observing her symptoms. 7/27/09 Consultant medical records received DOS 1/20/09 to 5/19/09. Includes neurodiagnostic reports from 12/8/08 and clinical labs from 12/6/08 to 12/26/08. Assessment: Anterior interosseous palsy due to Parsonage Turner syndrome /brachial neuritis. Patient presented with inability to flex left thumb. Tightness in cubital fossa. Weakness in the hand. Slight weakness in her EDP in her index. Strength is returning.

Other Meds:

Lab Data: EMG dated 2/06/2009 revealed a left anterior interosseous nerve syndrome. 7/27/09 Consultant medical records received DOS 1/20/09 to 5/19/09. LABS and DIAGNOSTICS: Normal EMG/Nerve conduction studies both upper extremities. Comprehensive

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 349407-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Feb-2008	25-Mar-2009	406	17-Jun-2009	18-Jun-2009	WV		25-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2329AA		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C2491AA		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	1176U		Unknown	Unknown	
	HEP	MERCK & CO. INC.	1106F		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bacteraemia, Conjunctival hyperaemia, Headache, Meningococcal infection, Myalgia, Pyrexia, Rash maculo-papular, Sepsis

Symptom Text: Patient developed bacteremia without focus and tested positive for Neisseria meningitidis from her blood. 6/24/09 Hospital records received DOS 3/27/09 to 4/3/09. Assessment: Neisseria bacteremia with early sepsis syndrome. Patient presents with maculopapular rash on wrists, palms, soles, and shoulder with fever. Headache, myalgia. Conjunctiva injected. ICD-9 Codes: 036.9, 782.1, 054.9

Other Meds:

Lab Data: Blood culture positive for N. meningitidis. 6/24/09 Hospital records received DOS 3/27/09 to 4/3/09. LABS and DIAGNOSTICS: Blood gram stain (+) for Neisseria meningitidis. Urinalysis (-). X-Ray Sinuses - Unremarkable. Chest X-ray - Negat

History: Unknown

Prex Illness: Unknown.

Prex Vax Illns: Unknown~Meningococcal (Menactra)~1~0~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349410-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	17-Jun-2009	17-Jun-2009	0	17-Jun-2009	30-Jun-2009	VA		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Loss of consciousness, Tooth fracture

Symptom Text: Wasnt told to wait immediately after vacine. Felt ok for a minute or so, got onto the elevator started to feel dizzy and blacked out and face planted into the tile floor out of the elevator. They checked my blood pressure immediately after and took me up to my general doctor for observation and took my blood pressure few more times after. Broke my 2 front teeth and will be needing dental cosmetic work done.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349419-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jun-2009	16-Jun-2009	0	17-Jun-2009	29-Jun-2009	NE		29-Jun-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1130X	0	Right leg	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B039AA	5	Left leg	Intramuscular	
VARCEL	MERCK & CO. INC.	0346Y	1	Left leg	Subcutaneously	
MNQ	SANOFI PASTEUR	U2873AA	0	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling, Pruritus

Symptom Text: Swelling and red reaction with induration approx. 10 cm in size less than 30 minutes following vaccination. These reactions noted at VARIVAX vaccine site. Applied ice pack and administered BENADRYL (liquid, PO) to patient. Patient stated site felt "itchy"; and stop itching.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 349455-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Mar-2008	01-Mar-2008	0	18-Jun-2009	19-Jun-2009	FR	WAES0906USA01696	19-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Fatigue, Incorrect route of drug administration, Neutropenia, Thrombocytopenia, Viral infection

Symptom Text: Information received from the foreign Health Authorities via Sanofi Pasteur MSD as part of a business agreement, concerning a 15-year-old female patient received the first and second dose of GARDASIL (S.C., batch number not reported) via subcutaneous route instead of intramuscular route in March and April 2009, on month apart. She had a history of chronic idiopathic thrombocytopenic purpura discovered at the age of 3 years old. The patient's thrombocytopenia had always remained stable around 60g/l. In July 2008, i.e. three months after the second dose of GARDASIL, the patient developed a thrombocytopenia at 14 g/l which necessitated a treatment by immunoglobulins and she was hospitalized. A clinical examination was performed on 18-Nov-2008. There was no hemorrhagic symptomatology, but signs of a viral syndrome were found. Thrombocytic count was at 133g/l. To be noted a neutropenia with neutrophils at 0.94 g/l, in a context of fatigue which was perhaps in connection with current viral syndrome. The patient was hospitalized for the events of fatigue and viral syndrome. It was decided not to administer the third dose of GARDASIL. At the time of reporting, the patient had recovered from thrombocytopenia and fatigue. The outcome of the viral syndrome was not provided. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as doubtful (S2 S1 T1) according to the foreign method of assessment. No further information expected. Other business partner numbers include E200904715.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, ??Jul08, thrombocytopenia at 14g/l; diagnostic laboratory test, 18Nov08, thrombocytic 133g/l; diagnostic laboratory test, 18Nov08, neutrophils, 0.94g/l, neutropenia; diagnostic laboratory test, thrombocytopenia r

History:

Prex Illness: Idiopathic thrombocytopenic purpura

Prex Vax Illns:

Vaers Id: **349456-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Jun-2009	19-Jun-2009	NJ	WAES0906USA01886	19-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Mitochondrial cytopathy, Surgery

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with GARDASIL. The patient received the first dose of GARDASIL and a week and half later she was scheduled to have heart surgery due to a hole in a heart that patient already had. Then after surgery the patient started to experience illness on a mitochondrial level. The physician stated that the patient was hospitalized due to surgery but did not specify how long the patient was in the hospital. Illness on a mitochondrial level was considered to be immediately life-threatening and disabling. At the time of this report, the patient was recovering. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Cardiac septal defect

Prex Vax Illns:

Vaers Id: 349457-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-May-2008	Unknown		18-Jun-2009	19-Jun-2009	FR	WAES0906USA01992	19-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0466U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Autonomic nervous system imbalance, Dizziness, Exertional headache, Hypothyroidism, Inflammation, Peripheral vascular disorder, Presyncope, Syncope, Vertebral artery hypoplasia, Vertigo

Symptom Text: Information has been received from a health authority under HA reference no. PEI2009012057. It was reported that a 13 year old female patient with a history of vegetative regulation disorder in the context of post inflammatory hypothyroidism and infection NOS who on 15-NOV-2007 and 24-JAN-2008 was vaccinated with the first and second dose of GARDASIL (both lot # 0354U; batch # NF58150). Dose 1 and dose 2 were well tolerated. The patient was vaccinated with the third dose of GARDASIL (lot # 0466U; batch # NG34890) on 27-MAY-2008. Since spring 2008 (exact date not reported) the patient developed dizziness, exertional headache during competitive swimming, peripheral circulatory disorder, pre-syncope and syncope. Routine laboratory findings showed normal results in APR-2008 and JUN-2008. EBV antibody test on 03-JUN-2008 showed a past EBV infection: EBV-VCA-IgG antibody: 283.0 E/ml EBV-EBNAI-IgG antibody: >600.0 E/ml Thyroid diagnosis on 18-JUN-2008: Suspicion of disseminated autonomy confirmed by a positive elevated TRH test. Sonography of the abdomen showed a left adrenal gland area with round, low echo and a well limited volume of 1.5 cm diameter. The patient was hospitalized from 20-AUG-2008 until 22-AUG-2008 due to clarification for dizziness attacks on exertion with syncope and pre-syncope. After an infection (not otherwise specified) at the beginning of 2008 the patient showed a marked lactate value. Additionally she had developed vertigo (onset not reported). Long-term medication with levothyroxine L-THYROXIN 200 ug. On 14-AUG-2008: Sonography of the abdomen showed normal results. Laboratory findings 22-AUG-2008: Borrelia antibodies (IgG and IgM) were negative. Free T4: 1.88 (slightly increased). On 20-AUG-2008: Echocardiography showed normal results. Stress ECG was discontinued by the patient due to vertigo, feeling of weakness, vegetative symptoms and affective reaction up to a level of exertion of 150 watts, otherwise normal findings. Duplex sonography showed hypoplasia of right vertebral artery compensated

Other Meds: L-Thyroxin

Lab Data: diagnostic laboratory test, ??Apr08, normal; diagnostic laboratory test, ??Jun08, normal; abdominal ultrasound, 18Jun08, a left adrenal gland area with round, low echo and a well limited volume of 1.5 cm; echocardiography, 20Jun08, normal;

History: Infection

Prex Illness:

Prex Vax Illns:

Vaers Id: **349474-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Jun-2009	17-Jun-2009	0	18-Jun-2009	29-Jun-2009	CO		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3068AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Hypotension, Hypoventilation, Somnolence, Syncope, Vomiting

Symptom Text: 06-17-09 Fainting episodes x2 after vaccines given. Recovered x1 after glass of water given. Second time it was difficult to wake her, shallow breathing, skin cold and clammy to touch. 911 called. Vomitted x1. BP-74/50, P-68. Prior to the 2nd fainting episode she had tonic clonic movements noted in arms, bilaterally, eyes rolled back, incoherent.

Other Meds: UNK

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: 349476-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Sep-2008	26-May-2009	257	18-Jun-2009	29-Jun-2009	FL		29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Uterine dilation and curettage

Symptom Text: Patient had vaccine 9/11/08 and became pregnant in 2/09. She then had a fetus that "was not thriving" and she had a D&C done 5/26/09. Please note: Patient also received Menactra Mafr Sanofi on 10/7/08 in the right arm Lot# U2734AA purchased with private funds. Given by same person at the same office location.

Other Meds:

Lab Data:

History: Allergic to Dimetane History of Infectious Mononucleosis 11/17/05

Prex Illness: None reported

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349491-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	04-May-2009	Unknown		18-Jun-2009	29-Jun-2009	OH		12-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2844AA	0	Left arm	Intramuscular	
HEP	MERCK & CO. INC.	1372U	1	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB215AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0523U	0	Right arm	Intramuscular	
VARCEL	GLAXOSMITHKLINE BIOLOGICALS	1910U	1	Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2620AA	0	Left arm	Intramuscular	
MMR	MERCK & CO. INC.	0454X	1	Right arm	Subcutaneously	
IPV	SANOFI PASTEUR	A04922	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Patient was entered into the electronic medical record as a female. The nurse gave the patient an HPV as indicated for female patients. Upon returning to the clinic in one month for additional vaccines it was discovered the patient was actually a male. No adverse symptoms were reported.

Other Meds: None

Lab Data: N/A

History: No known allergies

Prex Illness: None

Prex Vax Illns:

Vaers Id: **349510-1 (S)** **Related reports:** 349510-2; 349510-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Feb-2009	20-Feb-2009	0	18-Jun-2009	19-Jun-2009	ME	WAES0906USA02278	10-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from parents, a physician and a medical assistant concerning a 19 year old female with anxiety, depression, asthma, twitching and tremor and a history of spinal fracture who was vaccinated with three doses of GARDASIL. The patient received the first dose of GARDASIL (Lot# 660618/0572X) on 17-NOV-2008. The patient received the second dose of GARDASIL (Lot# 661766/0652X) on 20-FEB-2009. The patient experienced numbness and tingling after the second dose. The numbness and tingling was never reported to the physician. The patient received the third dose of GARDASIL (Lot# 661846/1312X) on 05-JUN-2009. Concomitant therapy included ZOLOFT, hydromorphone, albuterol, montelukast sodium (MSD) and HOMACCORD. The medical assistant also reported that the patient had received a influenza virus vaccine (unspecified) shot on 13-OCT-2008. No other vaccines was given at the time of the GARDASIL doses. The parents reported that on 08-JUN-2009 the patient experienced seizures after the third dose. The patient was hospitalized on 9-JUN-2009 until 11-JUN-2009. The patient was still having seizures even after she was discharged from the hospital. Full blood chemistry panel and electroencephalography (EEG) were performed (results not provided). According to the medical assistant, hospital records from the June 2009 admission had not yet been received by the physician's office, but a written chart note indicated that the event did not look like a seizure. Event was not considered as disabling or life threatening. The patient would see a neurologist on 24JUN-2009. At the report time the outcome was unknown. Additional information has been requested.

Other Meds: hydromorphone; SINGULAIR; ZOLOFT

Lab Data: electroencephalography, results not provided; full blood chemistry, results not provided

History: Spinal fracture

Prex Illness: Anxiety; Depression; Asthma; Twitching; Tremor

Prex Vax Illns:

Vaers Id: **349510-2 (S)** **Related reports:** 349510-1; 349510-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Jun-2009	08-Jun-2009	3	22-Jun-2009	29-Jun-2009	--		23-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Confusional state, Conversion disorder, Depressed level of consciousness, Muscle twitching, Myoclonus, Somnolence, Tremor

Symptom Text: My daughter had the 3rd shot of GARDASIL on Friday 06/05/2009. On Monday the 8th she started experiencing seizures. She was admitted to the hospital on Tuesday the 9th and kept for observation until the 11th. She has had up to 16 seizures in one day. The hospital released her but she still continues to seize. After doing research on-line I've discovered other have also had seizure activity with the GARDASIL vaccine. 6/29/2009 MR received for DOS 6/9-11/2009 with d/C DX: Pseudoseizure. 2' dx: Depression. Anxiety. L2 fx s/p MVA 3 weeks ago. Pt presented to ER after several episodes of twitching, shaking arms and legs, myoclonic jerking followed by somnolence/decreased responsiveness/confusion. Witnessed episode in ED and during EEG, not c/w seizures. Psych consult done and to continue with previously Rx'd meds. 10/21/09 ICD9 codes: 781.0, 300.00, 311, 493.90, V155.11

Other Meds:

Lab Data: EEG done in hospital on 6/10 - 6/11 for 24 hour period. Labs and Diagnostics: EEG abnormal, not seizures. Head CT (-).

History: depression/anxiety asthma seasonal allergies broken L2 fracture from recent car accident. PMH: Recent MVA with L2 fx. anxiety. panic attacks. depression

Prex Illness:

Prex Vax Illns:

Vaers Id: **349510-3 (S)** **Related reports:** 349510-1; 349510-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Jun-2009	06-Jun-2009	1	04-Oct-2009	07-Oct-2009	ME		09-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Blood potassium decreased, Dehydration, Electrolyte imbalance, Grand mal convulsion, Muscle twitching, Myoclonus

Symptom Text: Myoclonic twitching in legs and arms. Later developed into a tonic clonic seizure lasting a few minutes. Bought home, rested, had 2x more seizures. Had severe tonic clonic seizure was bought to hospital, admit for 3x days. MRI, CT, Blood tests, Urine tests,VEEG done. Electrolites off, dehydrated, Potassium low. VEEG came back normal, everything else in blood work came back normal. Released to go to neurologist in one week. Seizures still happening atleast 2x a day or more. Hopspitalized and bought to ER multiple times for cluster attacks of seizures.

Other Meds:

Lab Data: Multiple EEG and VEEGs, CBC, urine tests, CT scans, MRIs.

History: Asthma, allergies, broken back

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349511-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	10-Jun-2009	10-Jun-2009	0	18-Jun-2009	30-Jun-2009	VA		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0074Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Inappropriate schedule of drug administration, Injected limb mobility decreased, Injection site pain

Symptom Text: Started day of vaccine 17 hr HA and arm hurt at injection. Took EXCEDRIN - no relief. No redness at injection site. Pain L arm with movement at injection site. Has gotten worse x 2 day now getting better.

Other Meds: YASMIN.

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **349517-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-May-2009	28-May-2009	0	18-Jun-2009	30-Jun-2009	MA		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainted after injection. No adverse affects.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **349527-1** **Related reports:** 349527-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Jun-2009	15-Jun-2009	0	18-Jun-2009	30-Jun-2009	NC		23-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0490Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0100Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Confusional state, Decreased appetite, Dizziness, Dyspnoea, Fatigue, Feeling abnormal, Feeling hot, Gaze palsy, Hypotonia, Immediate post-injection reaction, Loss of consciousness, Musculoskeletal stiffness, Pallor, Parosmia, Presyncope, Syncope, Tremor, Visual impairment

Symptom Text: Pt. had fainting episodes with 1st dose of GARDASIL on 4/7/09. With this 2nd GARDASIL & within seconds pt. got pale, as she was laying down her eyes rolled back, got stiff & shook about 2-3 times. Resolved quickly. Physician came immediately & saw her recovered. Episodes of vomiting for 1 hr. Pt home. 9/22/09-records received for dates of service-6/26/09-8/13/09-neurology consult-evaluation for 2 episodes associated with Gardasil. Blacked out at time of injection-body stiffening and shaking eyes deviated upward. First event 4/7/09 C/O felt weird and ears heard rushing unable to see as black came into her vision. C/O being hot, lost consciousness and was limp. Confused regarding circumstances-no change in mental status. 2nd event 6/15/09-lost consciousness, stiffening and shaking of whole body, weak afterward, pale and greenish. Vomited. C/O abdominal pain and bothered by smells, dizzy and short of breath wi th stairs. Appetite decreased for 6 days. Follow-up visit 8/13/09-no further episodes of loss of consciousness or seizures. C/O vision will become black when changing from sitting to standing. C/O tired. Long history of being tired. Assessment: most likely represented convulsive syncope particulary given her history of other vasovagal presyncopal events.

Other Meds: None

Lab Data: No 9/22/09-records received- EKG sinus arrhythmis. EEG normal. Labs WNL.

History: None

Prex Illness: None

Prex Vax Illns: ~HPV (Gardasil)~1~17~Patient

Vaers Id: **349527-2** **Related reports:** 349527-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Apr-2009	09-Apr-2009	2	26-Jun-2009	29-Jun-2009	--	WAES0906USA03689	12-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Amnesia, Anxiety, Blindness transient, Convulsion, Dizziness, Gaze palsy, Immediate post-injection reaction, Loss of consciousness, Malaise, Musculoskeletal stiffness, Nausea, Pallor, Syncope, Tremor, Tuberculin test, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a mother concerning her 18 year old daughter with no medical history and drug reactions who on 09-APR-2009 was vaccinated with her 1st dose of GARDASIL, 0.5 ml, IM. She went blind, got dizzy and then passed out. She fully recovered that same day. On 15-JUN-2009, the patient was vaccinated with the 2nd dose of GARDASIL, 0.5ml, IM. There was no concomitant medication. Then she passed out immediately, and had 3 mini-seizures. The mother didn't know if there was blindness or dizziness because her daughter passed out immediately. Since then she had nausea and vomiting and couldn't keep anything down. The patient had recovered from the seizures and syncope, but her nausea and vomiting persisted. The patient had sought medical attention. There were no labs and diagnostic tests performed. The mother felt that her daughter's blindness and 3 mini-seizures were considered to be important medical events. Additional information has been requested. 7/13/09 Medical records received DOS 4/7/09 to 6/19/09. Assessment: Shuddering episode related to syncope. Post vaccination patient became pale, eyes rolled back, got very stiff, shook 2 or 3 times. Loss of memory during episode. 5 vomiting episodes later at home. Also received PPD that day. Nausea, abdominal pain, 'not feeling right'. Dizziness, anxiety.

Other Meds: None

Lab Data: None. 7/13/09 Medical records received DOS 4/7/09 to 6/19/09. LABS and DIAGNOSTICS: PPD (-). CBC - Lymphocytes 20.4% (L) Granulocyte 76.8% (H). CHEM - Protein Total 8.3 g/dL (H)

History: None. 7/13/09 Medical records received DOS 4/7/09 to 6/19/09.: Lesion (MRSA) on thigh drained 2 weeks prev.

Prex Illness:

Prex Vax Illns:

Vaers Id: 349542-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	08-Nov-2007	08-Nov-2007	0	19-Jun-2009	22-Jun-2009	NY	WAES0802USA04905	22-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received from a physician for the Pregnancy Registry for GARDASIL concerning a 22 year old female who on 06-SEP-2007 was vaccinated intramuscularly with her first dose of GARDASIL (lot# not reported). There was no concomitant medication. On 08-NOV-2007 the patient was vaccinated intramuscularly with her second dose of GARDASIL (lot# 659435/1265U) and was pregnant. The patient's LMP was originally reported as 08-NOV-2007 with a due date of 14-AUG-2008. However the follow up information indicated an LMP date of 29-Oct-2007 with an estimated delivery date of 06-Aug-2008. The patient had an ultrasound on 21-Dec-2007 and sought medical attention in the physician's office. Follow up information has been received from a certified medical assistant on 19-FEB-2009. It was reported that the patient delivered vaginally, a normal and healthy baby boy on 30-JUL-2008. His birth weight was 7 lbs 5 oz; length: 201/4"; Apgar 9/9. She mentioned that the patient was just in their office last week and "was doing fine." Pediatric medical records were received and reviewed and the following experience was identified: On 05-AUG-2008 the infant was seen in the clinic. The physician reported that the baby had plenty of wet diapers and had been eating well, but since yesterday his feeding had decreased. The diagnosis was decreased feeding x1 day and mom was to call if no improvement. On 07-AUG-2008, 08-AUG-2008 and 12-AUG-2008 the baby was again seen by the physician and continued to have poor feeding with stable weight but no gain. The mother reported that she had to wake him every 4 hours to feed and she couldn't get him to take more than 1 and a 1/2 oz at a time. On 12-AUG-2008, his weight was 6 lbs 15 ozs. The physician's plan was to put him on soy formula and if no change in weight would do some labs. On 15-AUG-2008 the baby was seen for weight check. His formula intake was still down. He was taking approximately 10 oz per day. His bowel movements (BM's) were "hard, pebble-like" and his gu

Other Meds: None

Lab Data: Ultrasound, 12/21/07, positive

History:

Prex Illness: Pregnancy NOS (LMP = 10/29/2007)

Prex Vax Illns:

Vaers Id: **349543-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	24-Oct-2008	01-Feb-2009	100	19-Jun-2009	22-Jun-2009	--	WAES0906USA02049	22-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received through the Merck pregnancy registry for GARDASIL from a registered nurse concerning a female patient who on 17-JUN-2008 and 24-OCT-2008, was vaccinated with first and second dose respectively of GARDASIL (dose, route and lot number not reported). The registered nurse reported that the patient found out that she was pregnant in February 2009, but "the baby stopped growing at 10 weeks" and she lost her pregnancy in March 2009. It was reported that the patient waited for one month following the loss and had became pregnant again (WAES 0906USA02053). The registered nurse reported that the patient was not pregnant at the time of her previous two vaccinations. Upon internal review, the baby stopped growing at 10 weeks and she lost her pregnancy were determined to be other important medical events. This is one of two reports regarding the same patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349544-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		19-Jun-2009	22-Jun-2009	--	WAES0906USA02099	22-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Systemic lupus erythematosus

Symptom Text: Information has been received from a physician who heard from the mother of one of his patients that she was told by a pediatric rheumatologist that a patient with a genetic predisposition for lupus (family members had lupus) was vaccinated with GARDASIL and actually came down with lupus as well. The treating rheumatologist was reported to have thought that the vaccine triggered the onset of the disease. Upon internal review, lupus was determined to be an other important medical event. The existence of an identifiable patient and reporter could not be confirmed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Predisposition to disease

Prex Illness:

Prex Vax Illns:

Vaers Id: **349545-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Mar-2009	01-Mar-2009	0	19-Jun-2009	22-Jun-2009	CA	WAES0906USA02310	22-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Computerised tomogram, Dyspnoea, Headache, Hypersensitivity, Injection site mass, Lymphadenopathy, Mass, Nausea, Nephrolithiasis, Nuclear magnetic resonance imaging, Rash, Ultrasound scan

Symptom Text: Information has been received from a 25 year old female with a history of overgrowth bacterial and "ZIPORO" (therapy unspecified) allergy who in March 2009, was vaccinated with the first dose of GARDASIL. Concomitant therapy included neomycin, erythromycin, "Saczimin" (therapy unspecified), NASOCORT and NASONEX. In March 2009, the patient had a large bump on her arm after the vaccination. Afterwards the patient experienced swollen glands, headaches, nausea, rash, loss of breath and kidney stones and was hospitalized. The patient had an outpatient visit in April, 2009. Her physician diagnosed her as having a yeast allergy. She underwent a CAT scan, MRI and ultrasound (results not reported). At the time of report, the patient's status was not recovered. The health care professional contacted during telephone follow-up could not supply the following information: dates of vaccination, dose number, lot number, date of event, recovery status. Additional information has been requested.

Other Meds: NASOCORT; erythromycin; NASONEX; neomycin

Lab Data: Unknown

History: Overgrowth bacterial

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **349546-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	24-Mar-2009	20-May-2009	57	19-Jun-2009	22-Jun-2009	FR	WAES0906USA02405	22-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0777X		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Epilepsy

Symptom Text: Information has been received from a Health Authority (local case IT238/09) on 08-JUN-2009. An 11 year old female with a negative family history for epilepsy was vaccinated on 24-MAR-2009 with one dose of GARDASIL (Lot # 0777X, Batch # NJ35170). On 20-MAY-2009 she presented with an afebrile epileptic crisis that lasted over 15 minutes and resolved after treatment with anticonvulsive drug (NOS) i.v. She was hospitalized and during admission a brain CT, an electroencephalography and an eye exam with fundus oculi were performed and were all negative. The outcome is recovered. Other business partner numbers included E2009-04770. The case is closed. No further information is available.

Other Meds: Unknown

Lab Data: head computed axial tomography, negative; electroencephalography, negative; ophthalmological exam, exam with fundus oculi was negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 349547-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Nov-2007	01-Jan-2008	61	19-Jun-2009	22-Jun-2009	FR	WAES0906USA02762	22-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute tonsillitis, Coma, Diarrhoea, Dyspepsia, Intensive care, Type 1 diabetes mellitus

Symptom Text: Case received from a consumer on 15-JUN-2009. It was reported by the father of a female patient that she was vaccinated at the age of 18-years with a third dose of GARDASIL (lot #, injection route and site not reported) in November 2007. In January 2008 the patient showed increased body temperature for about 2-3 days reiterating every other week until February 2008. Subsequently she developed a difficult digestion that leads to diarrhoea. On 25-MAY-2009 the patient went comatose and was admitted to intensive care unit. Undefined examinations diagnosed a type 1 diabetes mellitus. It was reported that on an unspecified date before this event experienced angina tonsillaris. The final outcome was not reported. Other business partner numbers include E2009-04849. No further information is available. Case closed.

Other Meds: Unknown

Lab Data: temperature measurement, Increased body temperature

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349548-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	24-Jun-2008	18-Mar-2009	267	19-Jun-2009	22-Jun-2009	FR	WAES0906USA02791	22-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1113U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chemotherapy, Mediastinum neoplasm, Non-Hodgkins lymphoma

Symptom Text: Case received from a healthcare professional on 08-JUN-2009. This case was linked with case E2009-03044 (WAES# 0904USA0133) (same reporter, same vaccine, similar event, but different lot# and batch #). It was reported by a pharmacist that an adult female patient with medical history of allergy to house dust and molds was vaccinated with a third dose of GARDASIL (lot # 1113U, batch # NH10090, injection route not reported) into the upper arm on 16-DEC-2008. Concomitant therapy include hormonal contraceptive. The patient developed mediastum tumor on unspecified date and diagnosis of Non-HODGKIN'S lymphoma was established on 18-MAR-2009. At the time of reporting the patient was still under treatment with chemotherapeutic scheme blemycin, etoposide, adriamycin, cyclophosphamide, vincristin, prednisolone, BEACOPP and had not yet recovered. First dose and second dose of GARDASIL (both lot# 1113U, batch # NH10090, were administered on 24-JUN-2008 first dose and 18-AUG-2008 second dose. Toleration was not reported. Non-HODGKIN'S lymphoma was considered to be other important medical event. Other business partner numbers include E2009-04717. No further information is available.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History:

Prex Illness: House dust allergy; Mycotic allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349553-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		19-Jun-2009	22-Jun-2009	FR	WAES0906MEX00007	22-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Dizziness, Syncope

Symptom Text: Information has been received from a physician concerning a 15 year old female who in approximately 2009 was vaccinated with GARDASIL first dose. Approximately 20 minutes after vaccine administration the patient experienced convulsion, faint and dizziness and was hospitalized (treatment received, final diagnose, dates or other details not reported). Causality and outcome are not available. After several attempts no further information could be obtained. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349554-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		19-Jun-2009	22-Jun-2009	FR	WAES0906USA02406	22-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epilepsy, Immediate post-injection reaction

Symptom Text: Information has been received from a gynecologist concerning a 13 year old female patient who was vaccinated with GARDASIL (lot #, injection route and site not reported) on an unspecified date. Immediately post vaccination, the patient had an epileptic seizure. The outcome was not reported. The reporting gynecologist considered that epileptic seizure was another important medical event. Other business partner numbers include: E200904823. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349555-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jan-2009	01-Apr-2009	90	19-Jun-2009	22-Jun-2009	FR	WAES0906USA02442	22-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Polyarthritis

Symptom Text: Information has been received from a General Practitioner (G.P) concerning a 15 year old female patient with a good general health status and no familial medical history who in January 2009 was vaccinated with the third dose of GARDASIL (Batch # not reported). It was reported that 3 months after vaccination, she developed a beginning of chronic evolutive polyarthrits. She was treated with non steroidal anti-inflammatory drugs. In addition, it was planned that she would be given methotrexate 10 mg per day. At the time of reporting, the patient had not recovered. The primary reporter considered chronic polyarthritis to be another important medical event. Other business partner numbers include: E2009-04846. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **349562-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	17-Jun-2009	18-Jun-2009	1	19-Jun-2009	29-Jun-2009	IA		29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Grandmother called clinic on 6/19/09 after child received third dose of the HPV vaccine on 6/17/09. Per Grandma, the child had no immediate problems following vaccination. On the morning of 6/18/09, child woke up with hives on both upper extremeties. On 6/19/09, child woke up to find additional hives on both upper extremeties, which also increased in size. Denies itching or difficulty breathing. No treatment had been administered at the time Grandma reported this event. Advised to utilize over the counter antihistamine for immediate symptom management and contact primary care provider for further instructions.

Other Meds: none reported

Lab Data: none at time of this report

History: none reported

Prex Illness: no

Prex Vax Illns:

Vaers Id: 349580-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Jun-2009	17-Jun-2009	0	19-Jun-2009	29-Jun-2009	GA		29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2911AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B039AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site haematoma, Injection site swelling, Injection site warmth

Symptom Text: Around 6-7 pm on 6/17/09, client had small bruise on R deltoid where 1 of the vaccines was administered. On 6/18/09, redness was noted to R deltoid and spread down to middle of the upper arm, along with being hot to touch and swollen. The evening of 6/18/09 mother and client applied rubbing alcohol to R deltoid and surrounding area 5-6 times. The morning of 6/19/09 the bruise is localized to the site of injection and continues to be redness, edema, and hot to touch. Rubbing alcohol applied by client to affected area twice before coming to HD to report.

Other Meds: MOTHER STATES NONE

Lab Data: none

History: MOTHER STATES NONE

Prex Illness: NONE

Prex Vax Illns: N/A~ ()~NULL~~In Sibling1|N/A~ ()~NULL~~In Sibling2|N/A~ ()~NULL~~In Patient

Vaers Id: **349586-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jun-2009	18-Jun-2009	1	19-Jun-2009	29-Jun-2009	IL		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB320AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2826CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Malaise, Pyrexia

Symptom Text: The day following administration of Hepatitis A, Meningococccal and HPV vaccine, 6-18-09, patient ran a fever of 100.6 degrees F and complained of headache and malaise. 6-19-09 patient reported symptoms had resolved with no other problems.

Other Meds: None

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349589-1** **Related reports:** 349589-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
1.0	F	15-Jun-2009	19-Jun-2009	4	19-Jun-2009	30-Jun-2009	MI		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left leg	Intramuscular	DTAP
	MNQ	SANOFI PASTEUR	U2910AA	0	Left leg	Intramuscular	PNC7
	TDAP	SANOFI PASTEUR	UF456CA	0	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: NONE

Other Meds:

Lab Data: NONE

History: THIS IS A FOSTER CHILD MOTHER WAS ON DRUGS AND ALCHOHOL USE. AND ALSO BABY HAS GERD.

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **349589-2** **Related reports:** 349589-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
1.0	F	15-Jun-2009	15-Jun-2009	0	08-Jul-2009	05-Aug-2009	MI	200902607	25-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2910A	0	Left leg	Intramuscular	DTAP
HPV4	MERCK & CO. INC.	0652X	0	Left leg	Intramuscular	PNC7
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB343AA	0	Right leg	Intramuscular	
TDAP	SANOFI PASTEUR	C3005	0	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Tremor

Symptom Text: A 1 year old female patient received a first time dose of ADACEL (lot number C3005) intramuscularly in the left thigh, MENACTRA (lot number U2910AA) intramuscularly in the right thigh on 15 June 2009 at 3:30 PM. At 10:00 PM the patient "had the shakes" which lasted until 4:00 AM. The patient's mother brought the patient to the emergency room following the inadvertent administration of the products. The patient was treated with a dose of TYLENOL. The patient's mother stated that the patient "seemed okay, but was not sure". Recovery status was reported as unknown. List of Documents held by Sender: none. Follow up information received on 15 July 2009 from a health care professional. Four weeks prior to vaccination, on 18 May 2009 the patient received a second dose of DAPTACEL (lot number C30818A) and PREVNAR (manufacturer Wyeth, lot number D39016) both intramuscularly in the right leg. On 15 June 2009 the patient received ADACEL in the right leg, previously reported as the left leg and GARDASIL (manufacturer Merck, lot number 0652X) intramuscularly in the left leg. The patient experienced the shakes off and on through the hours of 10 PM and 4 AM. During this time the patient did not lose consciousness or retain a fever. There was no health care professional present during the hours of 10 PM and 4 AM. The patient does not have a personal or family history of tremors. No further treatment was received or lab work was completed. The patient was seen in the emergency room for precautionary measures only. The child had recovered within a 12 hour period and was without any further incidents. List of Documents held by Sender: none.

Other Meds:

Lab Data: none reported

History: No prior family or personal history of tremors.

Prex Illness:

Prex Vax Illns:

Vaers Id: **349591-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Jun-2009	18-Jun-2009	1	19-Jun-2009	30-Jun-2009	AL		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Nodule, Tenderness

Symptom Text: Client reports back on 6-18-2009, one day after receiving dose #3 of HPV, that she now has Knots on back of head that are tender to touch. No problems with previous HPVs. Instructed client to see PMD today and report back to health dept.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349596-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-Jun-2009	16-Jun-2009	0	19-Jun-2009	30-Jun-2009	CA		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Oxygen supplementation, Syncope

Symptom Text: Patient became faint, diaphoretic and was eased onto the floor. Her VS stayed normal, she was given O2 and within 1 minute was conscious and oriented x 3. She left after resting 1/2 hour in good condition

Other Meds:

Lab Data: na

History: None

Prex Illness: no

Prex Vax Illns:

Vaers Id: 349604-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Mar-2009	25-May-2009	77	21-Jun-2009	29-Jun-2009	--		29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	000000	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Intracranial pressure increased, Neuralgia

Symptom Text: endocraneal hipertension after 1.5 months after the secon dosis and finally results in neuropatic pain (1 week after the first symptons)

Other Meds: NONE

Lab Data: colagenosis estudies(c3 c4 anas), RMN AND ANGIO-RMN, EMG, VDRL, PCR , LUMBAR PUNCTION WITH DIFFERENTS STUDIES FOR MENINGITIS,

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Jun-2009	11-Jun-2009	2	19-Jun-2009	30-Jun-2009	VA		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1605X		Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF456CA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Face oedema

Symptom Text: Facial edema (notable lips & (L) eye), SOB. BENADRYL & SOLUMEDROL given.

Other Meds: SUDAL 12; SINGULAIR

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349650-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Jun-2007	05-Jun-2009	718	19-Jun-2009	30-Jun-2009	MA		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426I	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Non-consummation, Papilloma viral infection

Symptom Text: Had PAP at Gyn which came back positive for high risk HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56 after receiving 3 dose GARDASIL 8/11/06, 1/2207, 6/13/07. Not yet sexually active during immunizations. Will undergo colposcopy.

Other Meds: CONCERTA 27mg

Lab Data: PAP smear

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **349665-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Mar-2008	21-Mar-2008	0	22-Jun-2009	23-Jun-2009	WA	WAES0807USA03017	23-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received from a 17 year old female, for the pregnancy registry for GARDASIL, with asthma and VICODIN allergy, who in January 2008, was vaccinated with the first dose of GARDASIL. On 21-MAR-2008, the patient received the second dose of GARDASIL. Concomitant therapy included albuterol. The patient reported that on 25-MAR-2008, she found out she was pregnant. On an unspecified date, the patient had a pregnancy test that was positive. At the time of the report, the patient was 22 weeks and 4 days gestation. Her LMP was 15-FEB-2008 and EDD 21-NOV-2008. The patient sought medical attention. Follow-up information was received from a nurse who reported that on 17-NOV-2008, the patient had a cesarean section done because her baby was in a breech position. The patient reported the baby's weight at birth was 7 pounds and 13 oz. At the time of the report, the patient reported that she had a six month old "healthy and big" baby who weighed 20+pounds. The patient stated that the baby had asthma, and an inhaler, but that he was doing ok with that; and that the doctors were trying to figure that out, but did not know if he had allergies or not yet. At the time of the report the patient stated that she was feeling better from the cesarean section but still felt a little tender sometimes. Additional information has been requested.

Other Meds: albuterol

Lab Data: beta-human chorionic, "positive"

History:

Prex Illness: Pregnancy NOS (LMP= 2/15/2008); Asthma; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **349666-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Aug-2008	18-Aug-2008	0	22-Jun-2009	23-Jun-2009	AL	WAES0808USA03705	23-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received through the pregnancy registry for GARDASIL from a registered nurse concerning a 14 year old female with no pertinent medical history and no history of drug reactions or allergies who on 18-AUG-2008 was vaccinated with the first dose of GARDASIL (lot#: 659653/1448U) 0.5ml IM. There was no concomitant medication. A subsequent pregnancy test on the same day was positive. No problems were reported. The LMP was "3 weeks ago" (on approximately 29-JUL-2008). The EDD is 05-MAY-2009. The patient sought unspecified medical attention. Follow up information has been received from a registered nurse concerning the 14 year old female patient who on an unspecified date had a pregnancy termination. Upon internal review, pregnancy terminated was considered to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: urine beta-human, 08/18/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 7/29/2008)

Prex Vax Illns:

Vaers Id: 349667-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Mar-2008	01-Sep-2008	154	22-Jun-2009	23-Jun-2009	TX	WAES0906USA02285	28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Bronchitis, Chest pain, Chronic fatigue syndrome, Contusion, Cough, Depression, Dyspnoea, Fatigue, Gene mutation, Hypophagia, Immobile, Immune system disorder, Infectious mononucleosis, Injection site pain, Malaise, Myalgia, Pain in extremity, Paralysis, Paranasal cyst, Postnasal drip, Rhinitis, Sinusitis, Splenomegaly, Surgery, Viral infection, Weight decreased

Symptom Text: Information has been received from a consumer concerning her approximately 17 year old daughter with no medical history or allergies who was vaccinated with three dose of GARDASIL. Concomitant therapy included "LOLESTRA". The consumer reported that after receiving the first and second dose of GARDASIL the patient experienced injection site soreness but then was fine. Then about three weeks after receiving the third dose of GARDASIL. The patient experienced bruising in her leg which caused immobility, which they thought was a blood clot so they took her to the emergency room and had to stabilize her leg and then shortly after the bruising cleared up. Then in September 2008 the bruising came back in her leg and starting in November 2008 the patient started to get sick constantly. The patient could not move, was very exhausted, lost about 7 pounds, could not eat, and had breathing problems. The patient was taken to a pulmonologist because her pediatrician thought she may have walking pneumonia, mono or asthma, but they were all ruled out. Then the patient was taken to a physician who ran a bunch of blood test, and computerized tomography scan (CT) of her brain and a magnetic resonance imaging (MRI) of her left leg. The MRI and CT scan came back fine, but the physician stated that through the blood work the patient's immune system was compromised and believed it was from GARDASIL " The patient then started to get a lot of sinus infections and developed cyst in her sinus so she had out patient surgery (name of hospital, address and phone number unspecified)." The consumer reported that in mid May 2009 the patient developed mono and had been doing better but still got exhausted pretty fast, and had missed about 45 days of school this past school year. The patient was seen by the pediatrician to seek medical attention. At the time of report, the patient was recovering. Upon internal review, mononucleosis and bruising in leg were considered to be disabling. Additional information has been requested. 7/24/09 Clinical s

Other Meds:

Lab Data: magnetic resonance, fine; head computed axial, fine; hematology, immune system is compromised. Labs: Spirometry WNL. O2 sat 97% on RA. H. pylori (+). Abd US WNL.

History: None PMH: scoliosis, costochondritis, sinusitis, pahryngitis, back pain, abdominal pain

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349668-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Mar-2009	04-Mar-2009	0	22-Jun-2009	23-Jun-2009	FR	WAES0906USA03000	23-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0512U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Palpitations, Psychomotor hyperactivity

Symptom Text: Information has been received from a Health Authority concerning a 13 year old female who on 04-MAR-2009 was vaccinated IM with the third dose of GARDASIL (lot # 0512U, batch # NG22320). On the same day the patient presented with headache, psychomotor agitation and cardiopalmus crisis and was hospitalized. An EEG was performed: slight slow anomalies in the temporal regions. ECG and routine lab work (NOS) within normal limits. Her condition improved. The final outcome was not reported. The case is closed. No further information is available. Other business partner numbers included: E2009-04979.

Other Meds: Unknown

Lab Data: electroencephalography, slight slow in the temporal regions; electrocardiogram, within normal limits; physical examination, within normal limits

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349669-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Jun-2009	23-Jun-2009	FR	WAES0906CAN00071	23-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Idiopathic thrombocytopenic purpura

Symptom Text: Information has been received from a mother concerning her daughter who was vaccinated with a first dose of GARDASIL. The mother reported that her daughter was "perfectly healthy and rarely enough got a cold". Subsequently the patient experienced chronic ITP. The mother reported that her daughter "will require treatments for the rest of her life". Upon internal review, chronic ITP was considered to be another important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349671-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-Jun-2009	19-Jun-2009	0	22-Jun-2009	30-Jun-2009	GA		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0162Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient in for doctor's visit and was ordered Gardasil vaccination. Patient received vaccination and was instructed to remain in waiting are for 20 minutes after immunization. Patient was apprehensive from begining and stated that she did not like needles. Patient left immunizations room and went to front desk to make appointment and had a syncope episode at front desk. When called to front desk a provider and staff were tending to patient by placing legs above heart and patient was awake and coherent.

Other Meds: Unknown

Lab Data: CBC, Basic Metabolic Panel, CT Scan of head and HCG Ql test performed. Blood test normal with only elevation in RBC and CT revealed unremarkable. HCG was also negative.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **349682-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Jun-2009	22-Jun-2009	0	22-Jun-2009	30-Jun-2009	NY		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Head injury, Pallor

Symptom Text: child received HPV and had fingerstick for hemoglobin. left exam room and was sitting alone in conference room began to feel light headed and was heard to hit her head on desk. She had not eaten breakfast. Child was kept on the floor and given oxygen and felt better. She again sat up and shortly afterwards became pale and light headed again and was laid down on the floor. She was sent to the ER for further evaluation and management since head trauma was unwitnessed

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **349690-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Jun-2009	09-Jun-2009	0	22-Jun-2009	30-Jun-2009	MN		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2664AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Excoriation, Fall, Immediate post-injection reaction, Laceration, Loss of consciousness, X-ray

Symptom Text: Patient was given a HPV injection and within seconds she fell over with loss of consciousness and jerking movements. Fell off of exam table. Pt. was taken to the ED and treated for a nasal laceration, eye abrasion and x-rays.

Other Meds:

Lab Data: N/A

History: No

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **349697-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
32.0	F	23-Oct-2007	22-Jan-2008	91	23-Jun-2009	29-Jun-2009	--		29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Inappropriate schedule of drug administration

Symptom Text: I took Gardasil 1st dose on Aug 23, 2007, 2nd dose on Oct 23, 2007. I got pregnant in Jan 2008. My unborn baby then diagnosed with ring chromosome 21 when he was 12 weeks. He was born with cleftlip, cleftpalate, undescended testis.

Other Meds:

Lab Data: Baby with ring chromosome 21 by mutation. Both husband and wife carry normal gene.

History: none

Prex Illness:

Prex Vax Illns:

Vaers Id: **349705-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Jun-2009	15-Jun-2009	0	22-Jun-2009	30-Jun-2009	NM		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Tonic clonic movements, Unresponsive to stimuli

Symptom Text: Patient became faint for about 15 seconds then woke up fine. Was checked (provider) then discharged. Was watched for 30-45 minutes. Pt had clonic-tonic movements for about 30 secs and unresponsive. When responsive-pt knew who she was, mom and where she was. RN.

Other Meds:

Lab Data: none

History: asthma

Prex Illness: none

Prex Vax Illns:

Vaers Id: **349725-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-May-2009	28-May-2009	0	22-Jun-2009	01-Jul-2009	OR	OR200924	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB262AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1487U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2662AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Headache, Heart rate normal, Nausea, Skin warm, Tremor

Symptom Text: Date: 5/28/09. Vaccines were administered and the patient remained in the exam room in a supine position for 15 minutes, with an additional 10 minutes spent in the clinic. One hour later, she presented to the school nurse with complaints of dizziness and nausea. Per the school nurse, her BP at that time was 88/62, pulse 96. (Her BP on previous exam ranged from 97/66 to 110/73). She had no dyspnea, pruritis, hives, diaphoresis, or mental status changes. Her nausea improved, but she complained of a headache after 15 minutes, at which point her BP was 88/64, pulse 76. At discharge home in the care of her parent, the school nurse also reported the patient's entire right arm was warm to the touch, with tremors. The patient experienced brief dizziness when she first sat up, but recovered quickly. OTC BENADRYL was administered by patient's mother. The patient returned to school the following day and reported no further episodes.

Other Meds: ORTHO CYCLEN

Lab Data:

History: allergic to horses

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349727-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	11-May-2009	11-May-2009	0	22-Jun-2009	01-Jul-2009	CT		01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Condition aggravated, Pruritus

Symptom Text: First GARDASIL given 5/11/09. She called my office on 6/17/09 to say she had itching in her fingers and water blisters after inj. She gets same rxn when exposed to sulfa.

Other Meds:

Lab Data:

History: Pt states sulfa allergy

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349728-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Jun-2009	18-Jun-2009	1	22-Jun-2009	01-Jul-2009	KY		01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0332Y	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1130X	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Woke up this am with shot area painful - per mother.

Other Meds:

Lab Data:

History: Developmental delay; Cerebral Palsy

Prex Illness: Poor wt gain

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349736-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Jun-2009	19-Jun-2009	0	22-Jun-2009	01-Jul-2009	NJ		01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC526029AA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Grand mal convulsion, Immediate post-injection reaction

Symptom Text: Seconds after PPD placement and GARDASIL < 10 second witnessed ?generalized tonic/clonic seizure. No post ictal no incontinence.

Other Meds: PPD

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349737-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jun-2009	22-Jun-2009	0	22-Jun-2009	01-Jul-2009	IL		14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2632AA	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0187Y	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	3	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea

Symptom Text: Pt started with dizziness and SOB

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **349803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	12-Apr-2009	12-Apr-2009	0	23-Jun-2009	24-Jun-2009	FR	WAES0905MYS00002	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal heart rate abnormal, Intra-uterine death

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with three doses of GARDASIL, intramuscular injection. The physician found out "later on" that the patient was "4 days pregnant when she received the last dose" (third dose) of the vaccine. The reporter felt that pregnant was not related to therapy with GARDASIL. On 7-MAY-2009, the following follow-up information was received: The patient is a 29 year old female with a history of 1 pregnancy and 1 live birth. On 12-APR-2009, the patient was vaccinated with the third dose of GARDASIL, intramuscular. Details of the first and second doses are unknown. Her Last Menstrual Period was on 20-MAR-2009. Estimated delivery date is 29-DEC-2009. The patient is not on any concomitant therapy. On 9-JUNE-2009, the following follow-up information was received: During the patient's first visit to the physician, the fetus "was fine"; "limbs were ok". On either the 2nd or 3rd visit which was last week (approximately 5-JUNE-2009), the physician noticed that the fetus had no heart beat. Subsequently, on approximately 5-JUNE-2009, the pregnancy was terminated. The baby did not suffer from any congenital anomaly. Upon internal review, no heart beat for the fetus and termination of pregnancy-elective were considered to be important medical events. Causality for the elective termination (for the mother) and no heart beat (for the fetus) are unknown. No further information is available.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 20Mar09)

Prex Vax Illns:

Vaers Id: **349805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Feb-2009	01-Feb-2009	0	23-Jun-2009	24-Jun-2009	--	WAES0906USA02881	24-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Anaemia, Blood test, Condition aggravated, Drug exposure during pregnancy, Uterine dilation and curettage

Symptom Text: Information has been received from a 21 year old female patient with a history of previous miscarriage and anaemia who in February 2009, was vaccinated with the first dose of GARDASIL (lot# not available). There was no concomitant medication. The Health Department that administered the vaccine did a pregnancy test but it came back negative. The patient thinks she may have been about 2 weeks pregnant at the time of the injection. On 07-MAY-2009 the patient had a miscarriage and the physician also discovered she had an anemia. A blood test and "D & C" (unspecified) were performed (no results provided). The patient sought unspecified medical attention. Upon internal review miscarriage was considered to be another important medical event. No further information is available.

Other Meds: None

Lab Data: beta-human chorionic, result negative

History: Miscarriage; Anaemia

Prex Illness:

Prex Vax Illns:

Vaers Id: **349807-1** **Related reports:** 349807-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-May-2008	01-Aug-2008	92	23-Jun-2009	24-Jun-2009	--	WAES0906USA02971	21-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Drooling, Dyskinesia, Hyperhidrosis, Incoherent, Partial seizures, Petit mal epilepsy, Posture abnormal, Speech disorder, Unresponsive to stimuli

Symptom Text: Information has been received from a physician concerning a 15 year old female with depression who in November 2007 was vaccinated with her first dose of GARDASIL intramuscular in her deltoid. Concomitant therapy included LEXAPRO. The patient was vaccinated with all three doses of GARDASIL (lot numbers not available) intramuscular into her deltoid. The patient received her first two doses of GARDASIL along with MENACTRA, Tdap (manufacturer unknown). Three or four months after receiving her third dose of GARDASIL intramuscular (in approximately August 2008 or September 2008), the patient experienced absent seizure. The child became non-reactive, non-responsive and distant. She did not received any other vaccines along with her third dose. She received an electroencephalography and an magnetic resonance imaging which were normal. The outcome of the patient was not reported. The patient was currently seeing a neurologist who felt that the seizure was caused by stress rather than from the vaccine. Upon internal review absent seizure was considered to be an other important medical event. Additional information has been requested. 10/19/09 Neurology consultation records received, service dates 4/7/09 to 10/5/09. Assessment: Partial epilepsy. Witnessed seizure with vocalization, elbow flexed, hand clenched, turned head to right side, incoherent. sweating and drooling.

Other Meds: LEXAPRO

Lab Data: Electroencephalography, normal; Magnetic resonance, normal

History: 10/19/09 Neurology consultation records received, service dates 4/7/09 to 10/5/09. Anxiety, dysthemia. Static encephalopathy. ADHD.

Prex Illness: Depression

Prex Vax Illns:

Vaers Id: **349807-2 (S)** **Related reports:** 349807-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		29-Sep-2009	05-Oct-2009	MO		27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Left arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abnormal behaviour, Acne, Convulsion, Electroencephalogram abnormal, Fatigue, Immediate post-injection reaction, Loss of consciousness, Nuclear magnetic resonance imaging normal, Rash, Speech disorder

Symptom Text: My daughter had her first dose of Gardasil in October of 2007, then her second dose November of 2007, and her last dose April 2008. Right after (approxamatly 1 month) her 3rd dose she started having spells that she would black out and be mumbling to where nobody could understand her. She just thought she was day dreaming and so she did not inform us. In the first of September of 2008, patient had came home from school and was very tired. She went up to her room and laid down for about 1 hour. Then she came down stairs and sat on our fireplace step and started talking totally out of her head and we could not understand her. Our first reaction was she was doing drugs and we was going to take her to her Pediatrician. The following week at her softball practice she did it again in front of her coach and father. Her father called me and I immediately called her pediatrician and made an appointment the next day. Her pediatrician told us to take her to a child Neurologist. We got in the following week with her Neurologists and he initially thought that it was her anxiety causing it. He did an EEG and that came back negative and then he did an Mri and that came back negative. Dr. then decided that it was probably caused by her anxiety and sent us to a child Phsyciatrist to have her tested. Still at this time Dr. wasn't sure if these were seizures. We then went and saw the Phsyciatrist and he did some testing and figured out it was not her anxiety and thought her anxiety wasn't that bad. We then had an appointment the next couple of days with her Neurologist. While at the appointment patient went into a seizure in front of the Dr. I had been explaining to him that they have been getting worse. Instead of having them maybe once a week she was having them 2 to 3 times a week and sometimes 2 or 3 times a day. Dr. stated while she was in the seizure that she was definitely having a seizure and I told him that this was the first time I had seen her posture. Dr. had an EEG done immediately and it did come back that the left sid

Other Meds: Lexapro, Minoocycline, Ziana Cream.

Lab Data: Epilepsy/Partial Seizures

History: Anxiety

Prex Illness: None

Prex Vax Illns:

Vaers Id: 349808-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jan-2008	01-Jan-2009	366	23-Jun-2009	24-Jun-2009	FR	WAES0906USA03027	24-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Dyskinesia, Fatigue, Hyperventilation, Influenza like illness, Muscle spasms, Muscular weakness, Syncope

Symptom Text: Information has been received from Health Authorities concerning a 17 year old female who was vaccinated with the 1st dose of GARDASIL in January 2008, the 2nd dose in April or May 2008 and the 3rd in August 2008. In January 2009, the patient presented with influenza-like episode during 15 days, with no fever. During a cross-country running at school, the patient collapsed at the end of the kilometer. It took her several hours to recover. One week later, still in January 2009, she experienced tetany seizures at the least effort, associated with hyperventilation, very intense muscle cramps and abnormal movements. The patient also had chronic fatigue and muscle weakness in January 2009. Complementary examination showed a negative blood work-up, a deficiency in erythrocytic magnesium and a negative infectious mononucleosis test. In March 2009, the patient experienced again a very severe tetany seizure which led to her hospitalization in neurology. The following work-up were normal: EEG, electromyography at test, CT scanner, muscle biopsy. However, lactate/pyruvate dosage, with or without garrot, was abnormal. Investigations were carried on concerning an enzymatic deficiency (results not provided). At the time of report, the patient had recovered from tetany seizure but not from chronic fatigue and muscle weakness. The Health Authorities assessed the causal relationship between the reported reactions and vaccinations as doubtful according to the foreign method of assessment. Other business partner numbers included E2009-05004. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, ??09, negative blood work-up; diagnostic laboratory test, ??09, Lactate/pyruvate dosage, with or without garrot, was abnormal; serum magnesium, ??09, deficiency in Erythrocytic magnesium; serum EPSTEIN-BARR virus

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **349809-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		23-Jun-2009	24-Jun-2009	--	WAES0906USA03450	24-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Convulsion

Symptom Text: Information has been received from a pharmacist concerning his friend's daughter who on unspecified date was vaccinated with a dose of GARDASIL (lot# not reported). After she got the vaccine while she was waiting at the physician's office she experienced seizure. Couple days later she experienced lost of short term memory. At the time on the report on 17-JUN-2009 the patient had not recovered. Upon internal review, seizure was considered to be an Other Important Medical Event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 349811-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Nov-2008	01-Apr-2009	151	23-Jun-2009	24-Jun-2009	FR	WAES0906USA03466	24-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cervix carcinoma

Symptom Text: Information has been received from a physician specialist concerning a 22 year old female patient with no relevant history who in November 2008, was vaccinated with the first dose of GARDASIL. In February 2009 the patient was vaccinated with the second dose of GARDASIL via intramuscular route in the arm. In October 2007 a smear had been performed and was normal. In April 2009, two months after vaccination, in situ cervical cancer was diagnosed, confirmed by colposcopy and biopsy. She was hospitalised on an unspecified date. At the time of reporting, the patient was on her way to recover. Other business partner numbers include: E2009-05024. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, ??Oct07, normal; colposcopy, ??Apr09, in situ cervical cancer; biopsy, ??Apr09, in situ cervical cancer

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349829-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	22-May-2009	Unknown		23-Jun-2009	06-Jul-2009	WA		06-Jul-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2732AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3028AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB286AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Vaccine given to early per manufacturer.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349840-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Jun-2009	18-Jun-2009	1	23-Jun-2009	30-Jun-2009	VT		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2911AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Feeling cold, Injection site pain, Palpitations

Symptom Text: pt's mother called pt complained of soreness at the site and feeling cold. The next day she c/o her heart racing and feeling some discomfort in her chest.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns: none~ ()~NULL~~In Patient

Vaers Id: **349841-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	22-Jun-2009	23-Jun-2009	1	23-Jun-2009	30-Jun-2009	TX		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Swelling face

Symptom Text: Called in by Father, stated school nurse called that daughter face was swollen. Father instructed to take daughter to ER.

Other Meds: none

Lab Data: unknown.

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **349853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Nov-2008	01-Dec-2008	25	23-Jun-2009	29-Jun-2009	MA		22-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Dysstasia, Erythema, Joint swelling, Pain in extremity, Tendon pain

Symptom Text: Swelling of both ankles, purple/red color on heals. Extreme pain in left ankle/ achillies tenden/ lower leg. Began December 08- Present. Can not stand or put pressure on left foot without pain. Gardasil Dose #1 9/20/07 Lot# 1060U Site RA

Other Meds: Ortho Tri-cycle

Lab Data: MRI of left foot- revealed bursitis and bone marrow edema to left calcaneus and talus. CT scan of left foot- normal. X-rays (twice) of left leg/foot- normal. Blood work- normal.

History: Allergy to amoxicillin and cefzil.

Prex Illness: None.

Prex Vax Illns:

Vaers Id: **349873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	15-Jun-2009	15-Jun-2009	0	23-Jun-2009	06-Jul-2009	CA		10-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Cyanosis, Gaze palsy, Muscle rigidity, Nystagmus, Tremor

Symptom Text: Seizure 3 hours post administration of HPV 1st seizure - no other risk factors. 7/9/09 Hospital ED records received DOS 6/15/09. Assessment: New onset seizure, possibly secondary to tramadol use. Relative reports that patient while on bus had an onset of shaking of upper extremities, right extremities in a 'frozen' kind of extension. Eyes rolled back, some saliva, lips turned blue. Patient woke up and was confused. Exam reveals only slight right lateral nystagmus. Medical Center and neurology referral and MRI suggested.

Other Meds: 7/9/09 Hospital ED records received DOS 6/15/09. Ultram

Lab Data: Went to ER. had CT scan & blood tests. 7/9/09 Hospital ED records received DOS 6/15/09. LABS and DIAGNOSTICS: CBC - HGB 11.8 g/dL (L) HCT 34.8% Neutrophil 67% (H) Lymphocyte 15% (L). Other labs and diagnostics WNL.

History: None. 7/9/09 Hospital ED records received DOS 6/15/09. Headaches

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349885-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Jun-2009	19-Jun-2009	1	23-Jun-2009	06-Jul-2009	NE		08-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2826A	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	01004	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF456CH	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Adacel given at the site of redness and swelling.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349897-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Jun-2009	19-Jun-2009	2	23-Jun-2009	06-Jul-2009	TX		06-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336DA	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B04DAB	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2873AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0294Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site swelling, Local swelling

Symptom Text: R arm swelling from elbow to neck. TX - BACTRIM 4 tsp po BID.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **349966-1** **Related reports:** 349966-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Mar-2009	26-Apr-2009	31	24-Jun-2009	25-Jun-2009	IL	200902647	25-Jun-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1312X		Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2580A	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B018BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Systemic lupus erythematosus

Symptom Text: This case was received from a physician on 18 June 2009. A 14-year-old female patient, with no reported medical history, received the following vaccinations on 26 March 2009: a first intramuscular right deltoid injection of MENACTRA (lot number U2580AA); a first intramuscular right deltoid injection of BOOSTRIX (GSK, lot number AC52B018BA); and an intramuscular left deltoid injection of GARDASIL (Merck, lot number 1312X). She was recovering from a cold at the time of vaccination. One month post-vaccination, the patient developed a rash on the left cheek. A few months later, she was diagnosed with Lupus. No additional information was reported. Additional documents held by sender: None.

Other Meds:

Lab Data:

History: No pre-existing medical conditions; was recovering from a cold at the time of vaccination.

Prex Illness:

Prex Vax Illns:

Vaers Id: **349966-2** **Related reports:** 349966-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Mar-2009	23-Apr-2009	28	24-Jun-2009	25-Jun-2009	IL	WAES0906USA03741	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Intramuscular	
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	DPP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Rash, Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on 26-MAR-2009 was vaccinated with the first and only dose of GARDASIL (lot # 661846/1312X) IM 0.5 ml. Concomitant therapy included DTaP (manufacturer unknown), MENACTRA and ADACEL. Prior to the vaccination, the patient had a small rash on her nose. However, 4 weeks after the vaccination, the patient developed more rashes on her face. The patient was referred to a dermatologist and was diagnosed with lupus and given the treatments for lupus. The patient had not recovered at the time of reporting. Upon internal review, lupus was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Rash

Prex Vax Illns:

Vaers Id: **349968-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Oct-2007	31-Mar-2009	526	24-Jun-2009	25-Jun-2009	NJ	WAES0906USA02582	25-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Antibody test, Blood grouping, Drug exposure during pregnancy, Full blood count, Laboratory test

Symptom Text: Information has been received from a certified medical assistant, for the pregnancy registry for GARDASIL, concerning a 20 year old female with a history of migraine who on 22-OCT-2007 was vaccinated with the first dose of GARDASIL. On 22-APR-2009 the patient received the second dose of GARDASIL, 0.5ml/IM. No other vaccines were administered at the time of either GARDASIL dose. On 08-JUN-2008 the patient had a pregnancy test done and the office found out that she was pregnant at the time of the second dose of GARDASIL. Other labs test performed were: CBC, ABO grouping, STD screen and antibody screen (results not reported). The patient's last menstrual cycle was the end of March 2009. The patient was scheduled for surgery to terminate her pregnancy on 17-JUN-2009 for personal reasons. On 18-JUN-2009 the certified medical assistant reported that the patient terminated her pregnancy on 17-JUN-2009 as scheduled. At the report time the outcome was unknown. Upon internal review termination of pregnancy was considered an Other Important Medical Events. Additional information has been requested.

Other Meds: None

Lab Data: serum beta-human, 06/08/09, pregnant

History: Migraine

Prex Illness:

Prex Vax Illns:

Vaers Id: 350006-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Jun-2009	19-Jun-2009	0	24-Jun-2009	30-Jun-2009	GA		06-Jul-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	SKBAC52B039AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	PMCU2911AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	MSD1130X	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	SKBAHAVB336AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood glucose normal, Dizziness, Oxygen saturation decreased, Pallor, Sleep disorder, Vertigo

Symptom Text: Client became pale and lightheaded at clinic, but recovered on own. Mother called in this AM to report taking client to ER on 06/19/09 PM near midnight due to c/o dizzy, room spinning when eyes closed, afraid to go to sleep, thinking she was going to pass out; says O2 was a little low, unsure how low, blood sugar was fine, vitals were ok, never seen by MD x 7 hours, left. Reports similar episode last PM, but not taken back to ER, plans to schedule appt with PHP today. RN encouraged f/u with PHP, discussed continued symptoms with District Immunization Coordinator.

Other Meds: None.

Lab Data: N/A.

History: None.

Prex Illness: None.

Prex Vax Illns:

Vaers Id: **350017-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	18-Jun-2009	19-Jun-2009	1	24-Jun-2009	29-Jun-2009	VT		11-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Chills, Dizziness, Dyskinesia, General physical health deterioration, Hyperhidrosis, Hypersomnia, Immediate post-injection reaction, Malaise, No reaction on previous exposure to drug, Presyncope, Tremor, Vaccination complication, Vomiting

Symptom Text: Right after i recieved the vaccination i did not feel well and slept all afternoon i recieved the shot in the morning. I was vomitting, almost fainted, sweating uncontrollably. Then my whole body was shaking and would not stop. This happened the morning after i recieved the vaccination. I was very dizzy and had to go to the emergency room that afternoon to recieve medicine to stop shaking, vomitting. I stayed in bed for two days straight sleeping. I was very dizzy. Now I still have stomach issues and my body and health does not feel the same. 6/29/09 Received ER medical records for 6/19/2009. FINAL DX: Vaccine reaction Records reveal patient experienced dizziness, chills, shakiness, vomiting x 1, near syncope x 1 day. No previous reactions to immunizations. Tx w/IVF & meds. Improved & d/c tohome w/anti vertigo meds. 8/10/09 Received PCP medical records for 6/18-19/09 Records reveal patient on antidepressant & requesting BCP. Meds adjusted & vax provided. 6/19/09 reported lightheadedness & shaking jerky movements of UEs. Sent to ER.

Other Meds:

Lab Data: Medical records received 6/29/09 LABS: WBC 14.1(H), ANC 12.13(H)lymphs 8%(L).

History: None Medical records received 6/29/09 PMH: nasal fx. Allergy: Keflex.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **350021-1 (S)** **Related reports:** 350021-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Aug-2007	01-Dec-2007	117	24-Jun-2009	29-Jun-2009	TX		09-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0014U	2	Left leg	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Acne, Deafness bilateral, Dizziness, Fatigue, Headache, Hearing aid user, Menorrhagia, Menstruation irregular, Mood swings, Palpitations, Pollakiuria, Spinal deformity

Symptom Text: Mom stated Pt developed hearing loss to both ears Dec 07 shortly after completing GARDASIL series. Dose #1 1/23/07 - Dose#2 3/29/07 - Dose#3 8/6/07 - Pt now wears hearing aids. 7/8/09 Medical records received DOS 8/6/07 to 6/24/09. Assessment: Hearing impaired in both ears. Patient's parent reports that child has failed school hearing test, now wears hearing aids. Acne, headaches, fatigue. Palpitations. Urinating more frequently. Dizziness. Mood swings. Menstrual cycles heavy and irregular. Thoracic spine, mild curvature to the left.

Other Meds: ADDERALL XR

Lab Data: failed school hearing test

History: 7/8/09 Medical records received DOS 8/6/07 to 6/24/09. ADD. Ingrown toenail. Acute bronchitis. Allergic rhinitis.

Prex Illness: acne; finger injury

Prex Vax Illns:

Vaers Id: **350021-2** **Related reports:** 350021-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	23-Jan-2007	Unknown		17-Jul-2009	17-Aug-2009	--	WAES0906USA04967	17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0014U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hearing aid user, Hearing impaired

Symptom Text: Information has been received from a registered nurse concerning a female patient who on 23-JAN-2007 was vaccinated IM with the first 0.5 mL dose of GARDASIL (lot # 653736/0014U), on 29-MAR-2007 was vaccinated IM with the second 0.5 mL dose of GARDASIL (lot # 653736/0868F), and 06-AUG-2007 was vaccinated IM with the third 0.5 mL dose of GARDASIL (lot # 653736/0014U). Concomitant vaccine administered on 21-AUG-2007 included Tdap. It was reported that on an unspecified date, the patient started experiencing hearing problems and was wearing a hearing aid. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350023-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	24-Jun-2009	24-Jun-2009	0	24-Jun-2009	06-Jul-2009	PA		07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3098AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness

Symptom Text: Pt. received Tdap and then GARDASIL. she was sitting on end of exam table talking. She stopped talking fell forward into my arms and I laid her back on exam table. Pt appeared to pass out for about 5 seconds.

Other Meds: CRYSELLE-28

Lab Data: None

History: None

Prex Illness: sore throat

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350031-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Jun-2009	16-Jun-2009	0	24-Jun-2009	07-Jul-2009	CA		07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0700Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Induration, Oedema peripheral, Pruritus, Skin warm

Symptom Text: Pt came in upper arm swelling, warm to touch with some induration. Pt c/o some itching, denies pain. Advised to use cold compress and take BENADRYL. Pt given Rx for AUGMENTIN 400mg - 51mg 15mL oral susp. to avoid infection.

Other Meds: FLONASE 50mcg/ACTUATION QD

Lab Data:

History: Pt allergic to BACTRIM

Prex Illness:

Prex Vax Illns:

Vaers Id: 350092-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	10-Sep-2007	14-Dec-2007	95	25-Jun-2009	26-Jun-2009	NC	WAES0802USA00127	26-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal disorder, Oblique presentation

Symptom Text: Information has been received through the Merck pregnancy registry from a physician concerning a 23 year old female who on 12-JUL-2007 was vaccinated with her first dose of GARDASIL (lot# 657736/0389U). On 10-SEP-2007 the patient was vaccinated with her second dose of GARDASIL (lot# 658558/1061U). On 10-JAN-2008 the patient was vaccinated with her third dose of GARDASIL (lot# 659653/1448U) and was pregnant. The patient was 6 weeks, 5 days. Concomitant therapy included prenatal vitamins. Lab tests performed included quantitative HCG, CBC, Progesterone, HIV, RPR, Rubella, RH type, ABO, antibody screen and sickle cell prep. The patient sought unspecified medical attention and her outcome was not reported. Follow up information was received from an assistant of physician which reported that they did not have pregnancy outcome information. Follow up information was received from a medical records manager at the OB office, for GARDASIL, a Pregnancy Registry product, concerning the patient who on 10-SEP-2008 (39.5 weeks from LMP) delivered a normal male infant (weighted 8 pounds, 15 ounces). The Apgar score were 8 and 9 respectively. The patient delivered by cesarean section with pre and post-operative diagnosis of oblique lie and suspected macrosomia. There were no complications in the pregnancy, and the patient had a normal glucose tolerance test. The patient recovered without complication as well, and the baby was fine at the postpartum visit. Upon internal review, oblique lie and suspected macrosomia were determined to be other important medical events as they resulted in a cesarean section. Additional information is not expected.

Other Meds: vitamins (unspecified)

Lab Data: complete blood cell; serum progesterone test; HIV antibody screen; Rapid plasma reagin; serum rubella IgG; serum gonadotropin-; erythrocyte ABO antigen; red blood cell antibody; hemoglobin S test; urine beta-human; Apgar score, 8/9; glucose

History:

Prex Illness: Pregnancy NOS (LMP = 12/14/2007)

Prex Vax Illns:

Vaers Id: **350093-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Mar-2008	19-Mar-2008	0	25-Jun-2009	26-Jun-2009	NC	WAES0803USA03943	26-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Uterine dilation and curettage

Symptom Text: Information has been received from a 16 year old female consumer for the Pregnancy Registry for GARDASIL concerning herself who on 19-MAR-2008 was vaccinated with her first dose of GARDASIL (lot# not reported). On the same day the patient had a positive pregnancy test in the office. Her estimated LMP was 25-FEB-2008. She sought unspecified medical attention. Follow-up information received on 13-JAN-2009 from a woman from a doctor's office indicated that they did not follow up with the patient after she became pregnant. The reporter provided the OB/GYN practice information. Follow-up information was received from a person from the doctor's office indicating that the patient had a miscarriage in early pregnancy and had a dilation and curettage on 25-MAY-2008. It was also reported that the patient did not receive GARDASIL in their office. Upon internal review, miscarriage was determined to be an important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic, 03/19/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 2/25/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350094-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Dec-2008	01-Dec-2008	0	25-Jun-2009	26-Jun-2009	CA	WAES0906USA03355	26-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a medical assistant concerning a female in her 20's, who in December 2008, was vaccinated with the first dose of GARDASIL 0.5 mL, I.M. After the patient received the vaccine, experienced seizure like symptoms that lasted couple of seconds. The patient was apprehensive and nervous before getting the shot. The patient has since received the second dose of GARDASIL without any problems. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Apprehension; Nervousness

Prex Vax Illns:

Vaers Id: **350095-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Dec-2008	27-Feb-2009	88	25-Jun-2009	26-Jun-2009	FR	WAES0906USA03449	26-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Optic neuropathy, Papilloedema

Symptom Text: Information has been received from by Health Authorities (under the references numbers: MP20090384, MP0900293) concerning a 22 year old female patient with no reported medical history, who was vaccinated IM with two doses of GARDASIL (batch number not reported) in December 2008 and February 2009 and she was also vaccinated IM with two doses of ENGERIX-B (GSK) (batch number not reported) on 6-FEB-2009 and 6-MAR-2009 respectively. On 27-FEB-2009, she presented with optic neuropathy and papilloedema, events which lead to her hospitalization. At the time of the reporting, the patient was on her way to recover. The Health Authorities assessed the causal relationship between the reported reactions and vaccination as "doubtful" (C1 S2 I1) according to country method of assessment. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350096-1** **Related reports:** 350096-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Jun-2009	16-Jun-2009	0	25-Jun-2009	26-Jun-2009	MS	WAES0906USA03836	12-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2660BA	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion, Convulsion, Dyskinesia, Fall, Head injury, Skin injury, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning her 13 year old daughter who on 16-JUN-2009 was vaccinated with the first dose of GARDASIL (dose, therapy route and lot # not reported). On 16-JUN-2009, the patient fainted and also had a seizure 10 minutes after the dose of GARDASIL was given. Nurse practitioner stated her daughter "fell off of the table and hit her head". The patient was taken to the Emergency Room (name of hospital was unspecified) but was not admitted. The patient had recovered. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested. 8/10/09 ER records received DOS 6/16/09. Assessment: Syncope - Vasovagal, scalp contusion. Patient passed out and hit head. Brief jerking. Contusion right parietal area.

Other Meds: Unknown

Lab Data: Unknown. 8/10/09 ER records received DOS 6/16/09. LABS and DIAGNOSTICS: CT - Right frontal scalp hematoma.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350096-2 (S)** **Related reports:** 350096-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Jun-2009	17-Jun-2009	2	29-Jun-2009	30-Jun-2009	--	WAES0906USA03863	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Fall, Grand mal convulsion

Symptom Text: Information has been received from a company representative concerning her neighbor's friend's daughter a 13 year old female patient who "earlier this week" on approximately 15-JUN-2009 was vaccinated with a dose of GARDASIL. The patient had two episodes of seizures starting 2 days after administration of GARDASIL on approximately 17-JUN-2009. The patient was currently in the hospital. The patient had not recovered. Additional information has been received from the field employee who provided the patient's name (date of birth, provider name and phone number unknown). The field employee reported while in the pediatrician's office and after the patient and received the second dose of GARDASIL, the patient fell on the floor and had a grand mal seizure. An ambulance took the patient from the physician's office to the hospital. The health care professional contacted during telephone follow-up could not supply the following information: date of birth, date of vaccination, dose number (if applicable), lot number (if applicable), date of event, hospital name (if applicable), healthcare provider name and contact information. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350097-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Jan-2009	Unknown		25-Jun-2009	26-Jun-2009	FR	WAES0906USA04051	26-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1050U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Cardiovascular evaluation, Guillain-Barre syndrome, Headache, Muscular weakness, Neurological examination, Pericardial effusion, Somnolence

Symptom Text: Case received from the Health Authority on 17-JUN-2009 under the reference number PEI 2009012220. The original reporting was done by an alternative healer (non-medical practitioner). It was reported that a 12-year-old female patient was vaccinated with a first dose of GARDASIL (lot # 1050U, batch # NH32130, IM, injection site not reported) on 09-JAN-2009. One day post vaccination the patient developed asthenia, headache and sleepiness which improved the following day. A few days later symptoms recurred and subsequently worsened. Pediatric, neurological and cardiac examinations were carried out and a mild pericardial effusion was diagnosed. Three weeks post vaccination the patient was very weak especially gait, posture and the left arm more than the right arm. GUILLAIN-BARRE syndrome was suspected. At the time of reporting to Health Authority on 25-FEB-2009 the patient had not recovered. Health Authority coded also myasthenia. GUILLAIN-BARRE syndrome, asthenia, headache, sleepiness and pericardial effusion were reported as other important medical event. Other business partner numbers include E2009-05040. No further information is available. File closed.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **350108-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Jun-2009	19-Jun-2009	0	25-Jun-2009	30-Jun-2009	NJ		18-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0389U		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood glucose normal, Convulsion, Dizziness, Loss of consciousness, Presyncope, Syncope, Tremor, Vision blurred

Symptom Text: Pt came to hospital for routine medical check up. 14 y/o female no past medical hx. Pt rec'd three immunizations GARDASIL-Merck Lot 0389U Exp 2/6/10; BOOSTRIX-Glaxo Lot AC52B029AA Exp 12/3/10; PPD-J & P Pharm Lot 84817 Exp 7/10. Pt had a syncopal episode accompanied by "Seizure like activity" lasting for approx 30 seconds. Following the procedure pt was Alert and oriented x 3. Blood Sugar: 89. IV started 1000cc .9 Nacl at 150/cc per hour. Transferred to ER for further evaluation. Pt left dept alert and oriented x3. No acute distress. 8/17/09 ER records received DOS 6/19/09. Assessment: Vasovagal reaction, syncope. Patient felt dizzy with some blurry vision and passed out. Shaking of legs and chest x4 seconds. Awake less than 30 seconds later. Returned to full consciousness without confusion. Seen and evaluated. Feels much better.

Other Meds:

Lab Data: PPD

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **350112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jun-2009	22-Jun-2009	0	25-Jun-2009	07-Jul-2009	MD		07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Immediate post-injection reaction, Loss of consciousness, Pallor, Syncope

Symptom Text: 45 to 60 seconds after injection, patient became pale, diaphoretic and fainted. LOC about 10-15 seconds. Responded to stimuli and had no other problems.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **350115-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Jun-2008	Unknown		25-Jun-2009	07-Jul-2009	AR	AR0926	04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0098X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression, Mood swings

Symptom Text: Mother and patient reports that patient felt depressed about two weeks after receiving GARDASIL. Also reports that she had mood swings. Did not see doctor at that time.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350121-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Jun-2009	17-Jun-2009	0	25-Jun-2009	07-Jul-2009	--		29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	2527CA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	06504		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Loss of consciousness

Symptom Text: pt sits on exam table - gave MENACTRA im to LD then HPV im RD. A few second later patient feels dizzy and passed out and lying on exam table, for about one minute then awake and talking but feeling tired. Apply O2 P = 64 BP = 100/64 observe 15 mn then discharge home in a good condition fully awake.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350124-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Jun-2009	Unknown		25-Jun-2009	07-Jul-2009	TX		07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF455AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB302BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2845AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None stated.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **350126-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Apr-2009	27-Apr-2009	11	25-Jun-2009	30-Jun-2009	TN		30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cranial nerve paralysis, Facial palsy, Lacrimation increased, Vision blurred

Symptom Text: Patient presented with Bell's Palsy on 4/28/09. Symptoms. Symptosm began on the 27th with right sided facial paralysis, blurred vision, excessive tearing. On exam she had finding c/w 7th nerve palsy. She treated emperically with prednisone and acyclovir. Symptoms persisted for several weeks and were fully resolved at her last visit on June 22.

Other Meds: None

Lab Data: EBV titers were c/w previous infection; IGM was <0.2. Strep culture was negative. An MRI of the brain was ordered by a neurologist and was normal on May 7.

History: Allergic to PCN (moderate non-specific rash). Allergic rhinitis.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350128-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Jun-2009	Unknown		25-Jun-2009	07-Jul-2009	TX		07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X		Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF471CA		Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB302BA	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None Stated

Other Meds: DRYSOL

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **350134-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	19-May-2009	19-Jun-2009	31	25-Jun-2009	30-Jun-2009	MA		06-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site nodule, Injection site pain

Symptom Text: 6/19/09 patient felt some pain in her upper left arm and felt a small bump.Seen at this office 6/25/09. She has a 1 cm soft cyst-like nodule which is in the general area of her Gardasil injection. No erythema, induration, heat. It is palpable but not visible.

Other Meds:

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350153-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jun-2009	16-Jun-2009	0	25-Jun-2009	07-Jul-2009	FL		07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Pt had a vasovagal reaction abut 5 mins. after administration. Pt responded immediately to verbal commands. She was oriented - kept pt until her mother came to pick her up (30 min-approx)

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350156-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	23-Jun-2009	24-Jun-2009	1	25-Jun-2009	07-Jul-2009	--		07-Jul-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1497X	0	Left arm	Unknown	
MNQ	SANOFI PASTEUR	U2910AA	0	Right arm	Unknown	
TDAP	SANOFI PASTEUR	UF46013A	0	Right arm	Unknown	
VARCEL	MERCK & CO. INC.	0336Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site cellulitis

Symptom Text: Cellulitis to R arm.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 350228-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Jun-2009	12-Jun-2009	3	26-Jun-2009	29-Jun-2009	FR	WAES0906USA04039	29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1477U	0	Unknown	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Asthma, Autopsy, Condition aggravated, Death

Symptom Text: Information has been received from a gynaecologist concerning an approximate 14 year old female patient with a history of bronchial asthma, who was vaccinated with a first dose of GARDASIL (lot # not reported) IM into the upper arm on 09-JUN-2009. On 12-JUN-2009, the patient experienced an asthmatic attack of which she died. The patient had no long-term medication for the asthma but only on occasion. Concomitant medication included hormonal contraceptives (unspecified). Reportedly, an autopsy was performed. The result is not yet known. A causal relation to the GARDASIL vaccine was considered unlikely by the vaccinating physician. Follow-up information received on 22-JUN-2009: Exact birth date, initials, height (158 cm) and weight (50 kg) as well as lot # 1477U, batch # NH25390 were provided. Following information gathered by phone from the reporting physician, the girl experienced the asthmatic attack at home and an emergency doctor was called. He was not able to arrest the attack and resuscitation was unsuccessful. Other business partner's numbers included: E2009-05085.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History: Asthma bronchial

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350234-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	05-Aug-2008	12-Aug-2008	7	26-Jun-2009	29-Jun-2009	NY	WAES0809USA00445	29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL concerning a 22 year old female with a history of papanicolaou smear abnormal and cervical dysplasia who on 05-AUG-2008 was vaccinated with a first dose of GARDASIL 0.5 ml IM in her left upper arm. Concomitant therapy included "FOUCACIO". On 02-SEP-2008 the patient went to the office and blood work was drawn. The patient was positive for pregnancy. No adverse event was reported. On 03-SEP-2008 the patient was 2 or 3 weeks gestation. The last menstrual period was approximately 12-AUG-2008. The estimated due date is 19-MAY-2009. Additional information has been received from a Pregnancy Registry memo. The patient underwent an elective termination of pregnancy prior to 20-OCT-2008 for reasons that are not related to the vaccine. Additional information has been requested.

Other Meds:

Lab Data: serum beta-human, 09/02/08, positive

History: Papanicolaou smear abnormal; Cervical dysplasia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 350235-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Jun-2009	13-Jun-2009	0	26-Jun-2009	29-Jun-2009	--	WAES0906USA02614	29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anxiety, Lethargy, Nausea, Pallor, Syncope

Symptom Text: Information has been received from a Physician Assistant (P.A) concerning a 15 year old female patient who on 13-JUN-2009 was vaccinated with the first dose of GARDASIL (Lot # not reported). It was reported that the patient fainted right after receiving the first dose of GARDASIL on 13-JUN-2009. It was reported that the patient was was brought to the emergency room and stayed there for a few hours. The patient was not admitted to the hospital. The patient sought medical attention with the Physician Assistant. There was a blood work performed (results not provided). It was reported that the adverse event had improved at the time of the report. All telephone attempts to contact the reporter have been unsuccessful. Follow up information was received from a Physician Assistant (P.A) on 23-JUN-2009 via telephone reported that the patient with no pertinent medical history or known drug allergies was vaccinated with the first dose of GARDASIL (Lot # 661846/1312X) on 13-JUN-2009. On 13-JUN-2009 the patient was very anxious and hadn't eaten since the night before. There were no concomitant medications and no other vaccinations given that day. After having fainted for only a few seconds, the patient was monitored in the office for the next 45 minutes. The vital signs and blood sugars were normal, but the patient was nauseous, lethargic and pale. She was transported to the emergency room. It was unknown what tests - other than blood work - were performed. The event was considered disabling for about five hours. The patient had fully recovered. The reporter considered fainted, nauseous, lethargic and pale to be significant disability/disabling. No further information is available.

Other Meds: None

Lab Data: vital sign, 06/13/09, normal; blood glucose, 06/13/09, normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **350237-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Apr-2009	27-Apr-2009	0	26-Jun-2009	29-Jun-2009	FR	WAES0906USA04044	29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse through the Health Authorities (reference number M200906-159) concerning a 14 years old female who experienced a general reaction or pruritus after receiving the first and second dose of GARDASIL (batch not reported). She received the first dose on an unspecified date. A few hours after vaccination, the patient had developed general pruritus which had begun in the joints of elbows, knees and spread throughout the body including genital area. The outcome was not reported. The patient received the second dose of GARDASIL (batch number not reported) via intramuscular route on 27-APR-2009 while she was in the emergency care service. Approximately 30 minutes later, she developed a similar reaction which was further exacerbated and which lasted two hours. She was given intravenous administration of an antihistamine (clemastine). To be noted that there was no history of previous adverse reactions to other drugs and that there was no suspicion of interaction. At the time of reporting, the patient had recovered. Other business partner number included: E2009-05145.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350238-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Jun-2009	12-Jun-2009	0	26-Jun-2009	29-Jun-2009	FR	WAES0906USA04045	29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0779X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Presyncope, Tonic clonic movements

Symptom Text: Case received from a physician on 18-JUN-2009 and transmitted through the foreign agency. A 17-year-old female patient received the first dose of GARDASIL (lot # 0779X, batch NJ32820) via intramuscular route on 12-JUN-2009. Approximately 5 to 10 minutes after vaccination, the patient experienced convulsion with tonic-clonic movements. The episode lasted around 1 minute, and the recovery was spontaneous and without sequelae. There was no loss of consciousness nor trismus. It was noteworthy that the physician reporter received the case from a nurse who mentioned that the convulsion have been epileptic. There was no known episode of fainting from blood collection or epilepsy. The physician reporter considered this case as non-serious. According to him, medically significant. Convulsion was considered to be other important medical event. Medically this was a vasovagal reaction and further dose would be administered to the patient under observation. To be noted that the case was also reported to the Health Authorities. Other business partner numbers include E2009-05164. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **350239-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		26-Jun-2009	29-Jun-2009	FR	WAES0906USA04053	29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Paraesthesia, Paralysis, Syncope

Symptom Text: Case received from the Health Authority on 17-JUN-2009 under the reference number PEI 2009012222. The case was linked with case E2009-5038 (same product, same reporter, same patient, different reactions). It was reported by a general practitioner that a female patient of unspecified age was vaccinated intramuscularly with a third dose of GARDASIL (lot #, injection site and date of vaccination not reported). Unspecified time post vaccination the patient experienced repeated syncopes. After second dose of GARDASIL the patient had already experienced palsy of the leg (E2009-05038; WAES # 0906USA04050). Palsy that was ongoing or recurring (not specified) was sometimes lasting for days. At the time of reporting (02-MAR-2009) the patient had been admitted to hospital five times by emergency doctor. Several investigations (unspecified) were carried out but didn't lead to any diagnosis. Toleration of first dose was not reported. After second vaccination with GARDASIL the patient experienced paraesthesia and palsy of her leg. At the time of reporting to Health Authority (02-MAR-2009) the patient had not recovered. Other business partner numbers include E2009-05052. No further information is available. File is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350240-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Jun-2009	12-Jun-2009	0	26-Jun-2009	29-Jun-2009	FR	WAES0906USA04256	29-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0779X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Presyncope, Tonic clonic movements

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 12-JUN-2009 was vaccinated with her 1st dose of GARDASIL (lot#0779X, batch#NJ32820), IM. Approximately 5 to 10 minutes after vaccination, the patient experienced convulsion with tonic-clonic movements. The episode lasted around 1 minute, and the recovery was spontaneous and without sequelae. There was no loss of consciousness nor trismus. It was noteworthy that the physician reporter received the case from a nurse who mentioned that the convulsion could have been epileptic. There was no known episode of fainting from blood collection or epilepsy. The physician reporter considered this case as non-serious. According to him, this was a vasovagal reaction and further dose would be administered to the patient under observation. To be noted that the case was also reported to the Health Authorities. Upon internal review, the event of convulsion has been considered as an other medical important condition. Other business partner numbers included E2009-05164. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350259-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Jun-2009	18-Jun-2009	1	26-Jun-2009	07-Jul-2009	AZ		08-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2930AA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: Erythema @ injection site

Other Meds: None

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **350284-1 (S)** **Related reports:** 350284-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Dec-2008	31-Dec-2008	2	26-Jun-2009	30-Jun-2009	CA		12-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Adverse drug reaction, Aphasia, Arthralgia, Arthritis, Autoimmune disorder, Butterfly rash, Chorea, Clumsiness, Confusional state, Encephalitis, Glomerulonephritis, Haematuria, Headache, Immediate post-injection reaction, Immunisation reaction, Joint effusion, Joint swelling, Memory impairment, Mouth ulceration, Musculoskeletal pain, Nephritis, Petechiae, Proteinuria, Purpura, Pyrexia, Rash, Screaming, Skin exfoliation, Synovitis, Systemic lupus erythematosus, Tongue eruption

Symptom Text: Immediately following vaccine, patient began to complain of mild symptoms (my shoulder hurts, my wrist hurts, look at these spots on my leg. On the 5th of January, she came home from school with pain in both of her ankles but after resting and and Advil, she felt ok to go school. She came home from school on the 6th screaming in pain. Her ankles were so swollen, we had a lot of trouble getting her boots off. She couldn't walk and had a rash all over her legs and ankles. We saw a pediatrician who immediately sent us to hospital. She had lots of tests and IV steroids and antibiotics. They later diagnosed her with Lupus. PCP records received as well as note from admission DOS 7/7-12/2009. Pt initially presented Jan 8, 2008 with c/o 5 day hx of bilateral ankle pain and rash of the ankle, calf and thigh. Seen in ER with PE (+) for petechial purpuric rash and low grade fever. Tx with abx and steroids and d/c for outpt f/u. Rheum consult PE (+) for L ankle effusion and decreased ROM. R ankle (+) for synovial thickening. Scant petechial lesions on LEs. ? Gardasil trigger for autoimmune disease with arthritis. F/U 1/15/09 with dx: Lupus. F/U 2/19/09, 4/6/09 with Impression: The presence of anti-histone AB suggests drug-induced Lupus 2' to Gardasil. F/U 6/22/09 with c/o H/A, joint pain, mouth sores and rash. Assess: Worsening Lupus now with nephritis. Admitted 7/7-12/09 with D/C DX: Lupus cerebritis, lupus glomerulonephritis for c/o difficulty with word finding and increasing clumsiness. Nephrology consult for hematuria and proteinuria. 7/31/09 Hospital discharge summary received DOS 7/7/09 to 7/12/09. Assessment: Lupus cerebritis, lupus glomerulonephritis. Patient presented with 6 days of increasing difficulty finding words and general confusion. Choreiform movements and difficulty with memory. Palmar peeling after Cytoxan treatment. Papules on tongue. Malar rash. ICD-9: Diagnosis 710.0 Systemic lupus erythematosus Other causes of encephalitis and encephalomyelitis: 323.814,

Other Meds: None

Lab Data: Blood work of DNA, ANA, complement levels. Urine analysis. X-rays of ankles. Later did Histone tests which indicated strong positive for Drug Induced Lupus. Labs and Diagnostics: Hgb low. Platelets low. BUN 25. AST/ALT in the 80's. C3/C

History: None. PMH: none. Sib with oligoarticular juvenile ideopathic arthritis and aunt with RA. Allergy to sulfa and augmentin. 7/31/09 Hospital discharge summary received DOS 7/7/09 to 7/12/09. Bactrim allergy.

Prex Illness: None

Prex Vax Illns: Periodic swelling of lip and eye~HPV (Gardasil)~1~9~Sibling

Vaers Id: **350284-2 (S)** **Related reports:** 350284-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Dec-2008	31-Dec-2008	2	13-Aug-2009	14-Aug-2009	--	WAES0907USA05121	14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Antinuclear antibody, Arthralgia, DNA antibody, Immediate post-injection reaction, Joint swelling, Musculoskeletal pain, Rash generalised, Screaming, Systemic lupus erythematosus, Urine analysis, X-ray limb

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 13 year old female patient with no known pertinent medical history and no known preexisting illness and with periodic swelling of lip and eye was vaccinated with the third dose of GARDASIL (Lot # 660612/0229X) intramuscularly on 29-DEC-2008. There were no concomitant medications. Immediately following vaccine, the patient began to complain of mild symptoms (shoulder and wrist hurts and spots on her legs). On 05-JAN-2009, she came home from school with pain in both of her ankles but after resting and an ADVIL, she felt ok to go to school. She came home from school on 06-JAN-2009 screaming of pain her ankles were so swollen, we had a lot of trouble getting her boots off. She could not walk and had a rash all over her legs and ankles. We saw a pediatrician who immediately sent the patient to hospital. She had a lot of test included blood work of DNA, ANA, complement levels, urine analysis, and X-rays of ankles. Later did histone tests which indicated strong positive for drug induced lupus. Intravenous steroids and antibiotics were prescribed. They later diagnosed her with lupus. The listing indicated that one or more of the events was considered to be disabling, was considered to be immediately life-threatening. No further information is available. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released. The original reporting source was not provided. The VAERS ID # is 350284.

Other Meds: None

Lab Data: Diagnostic laboratory, histone test indicated strong positive for drug induced lupus

History:

Prex Illness: Lip swelling; Eye swelling

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350305-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Jun-2009	12-Jun-2009	0	26-Jun-2009	08-Jul-2009	NJ		08-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Bronchospasm, Dysphagia, Dyspnoea, Hypersensitivity, Neck pain, Pain in extremity

Symptom Text: 30 minutes after receiving GARDASIL vaccine Pt. developed dyspnea, dysphagia, stabbing, sharp pain (R) arm and hip, neck pain. Dx: Allergic reaction. Bronchospasm.

Other Meds: None

Lab Data: Albuterol nebulizer tx in office for bronchospasm.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 350335-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Apr-2008	21-Apr-2008	0	29-Jun-2009	30-Jun-2009	--	WAES0810USA01631	30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a healthcare professional through a Pregnancy Registry for GARDASIL concerning a 17 year old female with depression, attention deficit disorder, obsessive compulsive disorder and post-traumatic stress disorder who on 20-FEB-2008, 21-APR-2008 and 26-AUG-2008 was vaccinated with the first, second and third dose of GARDASIL, the second dose on 21-APR-2008 and third dose on 26-AUG-2008 (lot#s 659653/1448U, unidentifiable and 660620/0571X respectively). Concomitant therapies included ABILIFY, PROZAC and TRILEPTAL. The patient's last menstrual period was reported as 08-AUG-2009, EDD: 15-MAY-2009. Follow up information was received from nurse in physician's office via a phone call who reported the patient had a termination in November 2008. The patient was doing fine and there was no sequelae from the vaccination. Upon internal review, a termination (abortion) was determined to be an other important medical event. Additional information has been requested.

Other Meds: ABILIFY; PROZAC; TRILEPTAL

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 8/8/2008); Depression; Attention deficit disorder; Obsessive-compulsive disorder; Post-traumatic stress dis

Prex Vax Illns:

Vaers Id: **350336-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Mar-2009	01-Apr-2009	13	29-Jun-2009	30-Jun-2009	FR	WAES0906COL00008	30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Dysaesthesia, Headache, Intracranial pressure increased, Myalgia, Nausea

Symptom Text: Information has been received from a physician concerning a 12 year old female who in January 2009, was vaccinated with GARDASIL. On 19-MAR-2009, the patient was vaccinated with the second dose of GARDASIL. In April the patient experienced headache, in May experienced nausea and continued with headache. On 08-JUN-2009 the patient was hospitalized, during the hospitalization lab exams were performed: clinical immunology test and magnetic resonance angiography of brain were normal. A spinal tap was performed, the diagnosis was Intracranial hypertension. On 13-JUN-2009 the patient experienced dysaesthesia and myalgia. Subsequently, on 14-JUN-2009 the patient recovered from headache and was discharged from the hospital on 16-JUN-2009 with the diagnosis of Intracranial hypertension. No more information about the hospitalization is available. The patient's dysaesthesia, nausea, myalgia and intracranial hypertension persisted. The reporter felt that dysaesthesia, myalgia and intracranial hypertension were not related to therapy with GARDASIL. Intracranial hypertension, dysaesthesia and myalgia were considered to be disabling. Additional information is expected.

Other Meds: Unknown

Lab Data: magnetic resonance angiography of brain, ??Jun09, Normal; spinal tap, ??Jun09, Intracranial hypertension; clinical immunology test, ??Jun09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350337-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	01-Jan-2008	01-Jul-2008	182	29-Jun-2009	30-Jun-2009	FR	WAES0906PNL00016	22-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician concerning her 28 year old female sister with a history of 0 pregnancies and 0 live births who in January 2009 was vaccinated with third dose of GARDASIL. There were no concomitant medications. Subsequently, she became pregnant on April 2008. In approximately July 2008, the patient experienced miscarriage after 10 weeks. Relationship of the miscarriage to therapy with GARDASIL is unknown. The reporter also mentioned that the patient later on became pregnant with her second child and is due to deliver the baby any time soon. Upon internal medical review, miscarriage was considered an other important medical event. This is one of two reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **350338-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
34.0	F	01-Dec-2008	01-Jun-2009	182	29-Jun-2009	30-Jun-2009	FR	WAES0906PHL00017	30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician concerning a 34 year old female with a history of 0 pregnancies and 0 live births who in December 2008, was vaccinated with third dose of GARDASIL. There were no concomitant medications taken. Subsequently, she became pregnant on March 2009. In approximately June 2009, the patient experienced miscarriage after 13 weeks. Relationship of miscarriage with GARDASIL is unknown. Upon internal medical review, miscarriage was considered an other important medical event. This is one of two reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 350339-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Jun-2009	18-Jun-2009	0	29-Jun-2009	30-Jun-2009	NJ	WAES0906USA03812	30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1131X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy, Muscle twitching, Nausea, Reaction to previous exposure to any vaccine, Syncope, Tremor

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 18-JUN-2009 was vaccinated IM, 0.5 ml with the first dose of GARDASIL (lot # 661954/1131X). On 18-JUN-2009 after being given GARDASIL, the patient "fainted and had shaking episodes and seizure like reactions. She regained consciousness and the shaking and seizure like activity stopped, but then started again." The adverse effect "stopped and started over a 3 hour period before she was ready to leave." The mother said that the patient was "fine" by then, but also said that the patient had "similar reactions" to "other vaccines" in the past. The doctor did not specify which vaccines the patient had the reaction to. The patient sought unspecified medical attention. The patient had recovered on 18-JUN-2009. Additional information has been received from a medical assistant on 22-JUN-2009 who reported the patient had no pertinent medical history other than the fact that the patient had "similar reactions" to childhood vaccines (no specifics available). The patient had no known drug allergies (NKDA). Concomitant therapy included SOLODYN and unspecified oral contraceptive. No other vaccines were administered at that time. Seizure like symptoms included twitching and eye rolling. The patient also had mild nausea. Blood pressure (B/P) at start of incident was 90/60; later it was 118/60. The patient did not go to the emergency room (ER). Event not considered as life threatening. Upon internal review, it was determined that eye rolling/twitching (convulsion) were serious as an other important medical events. No further information is available.

Other Meds: Hormonal contraceptives; SOLODYN

Lab Data: Blood pressure, 06/18/09, 90/60; Blood pressure, 06/18/09, 118/6

History: Vaccination adverse reaction

Prex Illness:

Prex Vax Illns:

Vaers Id: **350341-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Jun-2009	30-Jun-2009	FR	WAES0906USA04050	30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Asthenia, Paraesthesia, Paralysis

Symptom Text: Information has been received from by Health Authority (reference number: PEI2009012232) and general practitioner, concerning female patient of unspecified age, who was vaccinated IM with the second dose of GARDASIL (date, injection site and batch number not reported). On unspecified time post-vaccination the patient experienced paraesthesia and palsy in her leg. Temporarily she was so weak that she even could not walk. The patient was admitted to hospital. Several investigations (unspecified) were carried out but did not lead to any diagnosis. Toleration of first dose of GARDASIL was not reported. At the time of reporting to Health Authority (02-MAR-2009), the patient had not recovered. Other business partner numbers include E2009-05038, E2009-05052 (WAES# 0906USA04053, same product, same reporter, same patient, different reactions). File closed. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 350342-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Jun-2008	12-Jun-2008	0	29-Jun-2009	30-Jun-2009	FR	WAES0906USA04055	30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Enuresis, Presyncope, Schellong test, Syncope, Tonic clonic movements

Symptom Text: Information has been received from gynecologist concerning 17 year old female patient with a history of syncopes for instance when she suffers from nausea (She was able to describe these situations accurately). Also other members of her family have circulatory reactions the scope of low blood pressure and her mother had migraine. On 12-JUN-2008, the patient was vaccinated IM with a second dose of GARDASIL (lot number and injection site not reported). after vaccination the patient experienced a syncope with tonic-clonic movements and enuresis. In hospital letter it was written that she was reoriented after 20 seconds. on the reporting form duration was reported as five minutes. After putting her in another position symptoms improved. She was admitted to hospital (12-Jun-08 to 13-JUN-08). Physical examination and lab findings showed normal results. An EEG (electroencephalography) showed stable alpha EEG with slight increase of cerebral excitability. A single graphoelement was suspected to be a sharp slow wave. Hyperventilation showed generalized paroxysm that lasted for about 2 seconds (suspicious of spike slow wave) and after hyperventilation another generalized paroxysm was seen. Schellong test was normal. The hospital physicians came to the diagnosis of convulsive syncope in the scope of vasovagal reaction caused by vaccination. No anticonvulsive treatment was given. EEG controls were recommended. Concomitant medications included hormonal contraceptives (unspecified). The patient had recovered completely (unspecified date reported). Other business partner numbers include E2009-05066. File is closed. No further information is available.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: electroencephalography, Stable alfa-EEG-see narrative; orthostatic hypotension measurement, Normal; physical examination, normal; diagnostic laboratory test, Normal

History: Syncope; Nausea

Prex Illness:

Prex Vax Illns:

Vaers Id: 350343-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	20-Apr-2009	20-Apr-2009	0	29-Jun-2009	30-Jun-2009	--	WAES0906USA04118	30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Dizziness, Dyspnoea, Headache, Nausea

Symptom Text: Information has been received from a healthcare student concerning a 19-year-old female patient who was vaccinated with the first dose of GARDASIL on an unspecified date. After receiving the vaccine the patient developed dizziness, nausea and difficulty breathing. The patient had sought office visit medical attention. At the time of the report, the patient's status was recovered. The patient's dizziness, nausea and difficulty breathing was considered to be life threatening. Additional information from a phone call to a nurse stated that the patient received the first dose of GARDASIL (Lot# 661953/1130X) on 20-APR-2009. There were no concomitant vaccinations given at that time. Approximately 30 minutes after the patient received the GARDASIL (Lot# 661953/1130X) vaccination she had dizziness and nausea. On 21-APR-2009, the patient had difficulty breathing and had a headache. The patient went to her PCP to sought medical attention, and was given BENADRYL (route not reported). The patient came to office on 22-JUN-2009 for the second GARDASIL vaccination. The N.P. stated that she did not administer the GARDASIL vaccination. The N.P. stated that she felt the patient's difficulty breathing was considered life-threatening. Additional information from a phone call to the patient's PCP doctor reported that on 22-APR-2009 the patient was seen by a P.A. The patient complained of having difficulty breathing. The P.A. did not think that the patient's difficulty breathing was related to the GARDASIL vaccination. The P.A. documented that she thought the difficulty breathing was "coincidental and was possibly due to a viral infection". The patient was prescribed a MEDROL (DOSE PACK). The P.A. documented that she wanted to speak with the patient's GYN physician before the patient received the second dose of GARDASIL. The patient had not been back to the doctor's office since 22-APR-2009. No further information is available.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350344-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Jun-2009	22-Jun-2009	0	29-Jun-2009	30-Jun-2009	--	WAES0906USA04162	30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Immobile

Symptom Text: Information has been received from a consumer concerning his fiancee who on 22-JUN-2009 was vaccinated with the first dose of GARDASIL. Subsequently, the patient "could not get up" after vaccination. Then the patient was hospitalized. At the time of the report, the patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 350345-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jan-2009	03-Mar-2009	46	29-Jun-2009	30-Jun-2009	FR	WAES0906USA04236	30-Jun-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Clonus, Convulsion, Depressed level of consciousness, Dizziness, Epilepsy, Hypotonia, Loss of consciousness, Neurological examination normal, No reaction on previous exposure to drug, Petit mal epilepsy, Syncope, Trismus, Unresponsive to stimuli

Symptom Text: Information has been received from Health Authority on 24-APR-2009 under HA reference # PEI2009008420. It was reported that a 14 year old female patient was vaccinated with a second dose of GARDASIL (Batch # "NH21130" valid for PNEUMOVAX 23) (injection site not reported) intramuscularly on 16-JAN-2009. On 03-MAR-2009, the patient developed epileptic seizures with consciousness clouding, duration: 2 days (as documented). Under anticonvulsive treatment with ORFIRIL the symptoms stopped, but the patient had not recovered at the time of reporting (as documented). Dose one of GARDASIL (Lot # 3050U and Batch # NH32130) on 18-DEC-2008, intramuscularly was well tolerated. Follow up information was received on 18-JUN-2009. Two hospital reports were provided. The patient was hospitalized from 03-MAR-2009 until 18-MAR-2009. It was reported that the patient felt dizzy and collapsed in school on 03-MAR-2009. She had already been hospitalized for a similar event two years ago. The patient had no further medical history. The neurological investigation showed normal results. Lab parameters: c-ANCA and p-ANCA negative, infection serologies showed no evidence for an active infection with CMV, EBV, HSV 1 or 2, VZV, measles, rubella, coxsackievirus, mumps, echovirus, borrelia, toxoplasma, parovirus B19 or enterovirus. Liquor showed no pathologies. Repeated EEGs were normal. Routine laboratory findings were normal. The cranial computed tomography raised the suspicion of a 7 mm sized lesion of brainstem in medulla oblongata. No significant contrast agent absorption. Cranial MRI was normal. For the first time on 03-MAR-2009 the patient experienced epileptic like symptoms with unconsciousness, hypotonia, unresponsiveness to pain stimuli, Lockjaw and clonia of the right foot. Under treatment with LUMINAL and DIAZEPAM symptoms improved after about 45 minutes. The next day she experienced 3 further seizures. Due to the suspicion of atypical absences epilepsy treatment with VALPROAT was started and seizure episodes stopped. A psychiatrist s

Other Meds: Unknown

Lab Data: electroencephalography, normal; head computed axial tomography, raised the suspicion of a 7 mm sized lesion of brainstem in medulla oblongata; magnetic resonance imaging, cranial: normal; serum C-ANCA, negative; serum P-ANCA, negative; clin

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **350352-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Feb-2009	09-Feb-2009	0	29-Jun-2009	01-Jul-2009	IL		01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Hypotonia, Muscle tightness, Myalgia

Symptom Text: For 2 days, pt experience moderate intense muscle tightness and aching and a sense of limps feeling limp. This interfered with her ability to play sports.

Other Meds: None

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Jun-2008	15-Jan-2009	218	29-Jun-2009	01-Jul-2009	GA		06-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	UNK

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Sinusitis, Swelling face, Urticaria

Symptom Text: Chronic Hives...They were first noticed around mid January 2009. We first saw our pediatrician who thought it was viral. Then we went to see an Allergist who noticed she had a sinus infection. She has been on prednisone for facial swelling, Xyzal, Cingular, Benedryl, Zyrtec and 3 different antibiotics. She has had her blood drawn 4 times to see if there is anything serious like lupus or thyroid. Everything is fine. She has just had sinus surgery for her chronic sinus infection. We were hoping this was the case but her hives had been much worse since the surgery on June 24, 2009. My instincts have always told me it was a reaction to Gardasil. I have been hoping it was the sinus infection but it looks like it is not.

Other Meds:

Lab Data:

History: Allergic to Bioxin

Prex Illness: No

Prex Vax Illns:

Vaers Id: **350359-1 (S)** **Related reports:** 350359-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	24-Jan-2009	28-Jan-2009	4	29-Jun-2009	30-Jun-2009	MA		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Right arm	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	AC52B030AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Behcets syndrome, Genital herpes, Genital ulceration, Headache, Herpes virus infection, Hypophagia, Meningitis aseptic, Mouth ulceration, Nausea, Oral contraception, Oral disorder, Pyrexia, Rash, Rash papular, Skin hyperpigmentation, Tongue ulceration, Vaginal lesion, Vomiting, Vulval disorder, Vulvovaginitis

Symptom Text: First event 4 days after vaccine (2nd) dose...vaginal lesions, nausea,vomitting, headache -E.R visit diagnosed with herpes, all subsequent tests negative - 6/7/09 headache, fever, lesions: mouth and vaginal, aspetic meningitis, hospitilized for 5 days- diagnosed with Behcets disease 7/16/09 Medical records received DOS 7/25/07 to 7/08/2009. Assessment: Meningitis, viral unspecified. Behcet's Syndrome. Patient presents with papular lesion on outer vaginal opening. Vulva - White papular lesions. Vulvovaginitis. Increasing painful multiple ulcers vaginal area, purulant discharge, pain with urination. Genital herpes. Wart right hand. Vulvovaginitis. Hospitalized for viral meningitis. Rash: torso and arms -hyperpigmented patches, legs - flesh colored nontender papules. Consultation note: Oral-genital ulcers with papular rash and meningeal symptoms. 7/16/09 Hospital discharge summary DOS 6/14/09 to 6/17/09. Assessment: Behcets Patient presents with 3 days of severe frontal headache. 2 oral ulcers on tongue and 4 genital ulcers. Intermittant raised rash on torso and extremities. Nausea and vomiting. Not taking adequate PO.

Other Meds: birth control,prozac. 7/16/09 Medical records received DOS 7/25/07 to 7/08/2009. Oral contraceptives Lo/Ovral, Gyne-Lotrimin, Prozac, Bentyl.

Lab Data: MRI, CAT Scan, Lumbar puncture, blood tests. 7/16/09 Medical records received DOS 7/25/07 to 7/08/2009. LABS and DIAGNOSTICS: ESR 22 mm/hr (H) CBC - RBC 4.15 M/MM3 (L) MONO 9.2% (H) 7/16/09 Hospital discharge summary DOS 6/14/09 to 6/17/09

History: 7/16/09 Medical records received DOS 7/25/07 to 7/08/2009. Penicillin allergy, C. Trachomatis, Anxiety disorder.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **350359-2 (S)** **Related reports:** 350359-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	29-Jan-2009	Unknown		16-Jul-2009	21-Jul-2009	MA		21-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1129X	1	Right arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blood test normal, Culture negative, Headache, Pyrexia, Vaginal discharge, Vaginal lesion

Symptom Text: Patient developed vaginal lesions & discharge 4 d after 2nd HPV vaccine. Had febrile illness with copious vag discharge. Believed to be HSV infection but cultures & subsequent blood tests all neg. Repeat of vaginal lesions in 6/09. Again fever & headache. Now being evaluated by Doctor. Thought to have Behcet's Disease.

Other Meds: LO/OVRAL

Lab Data: attached

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **350361-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Jun-2009	29-Jun-2009	0	29-Jun-2009	01-Jul-2009	PA		01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2868AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB262BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0558X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2773BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Cold sweat, Dizziness, Nausea, Pallor

Symptom Text: Patiet received Menactra, Gardisil, Adacel, and, and Havrix. She became pale and nauseated. Her skin was cool and clammy. Her head went down appearing as if she was faint, but she was able to hear and answer questions. Spirits of ammonia applied. BP was 70/40. She was then placed in a supine position with legs elevated. Her symptoms then subsided and BP returned to 110/70. She stayed at the state health center for one hour accompanied by her mother who drove her home.

Other Meds: none

Lab Data:

History: none known

Prex Illness: none

Prex Vax Illns:

Vaers Id: **350390-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	10-Jun-2009	10-Jun-2009	0	29-Jun-2009	09-Jul-2009	IN		15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Intramuscular	
	VARCEL	GLAXOSMITHKLINE BIOLOGICALS	0260Y	1	Left arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB282AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Immediate post-injection reaction, Pallor, Syncope, Unresponsive to stimuli

Symptom Text: Client immediately suffered syncope episode after injection of GARDASIL. She was pale, clammy to touch and non-responsive for approx 1 minute. BP 77/54. Client awoke, was given sprite to drink and was observed for approx. 20 min. Client appeared fully recovered when she left with her mother. Followed-up 6/26/09, mother states client is well.

Other Meds:

Lab Data:

History: Allg.; PCN

Prex Illness: None

Prex Vax Illns:

Vaers Id: 350414-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Jan-2009	20-Jan-2009	0	29-Jun-2009	06-Jul-2009	CA		09-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0270		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1311X	2	Unknown	Unknown	
	MMR	MERCK & CO. INC.	0812U		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Cat scratch disease, Eye pain, Headache, Intraocular pressure increased, Myodesopsia, Photophobia, Photopsia, Retinal vasculitis, Retinitis, Trabeculectomy, Uveitis, Vision blurred, Vitritis

Symptom Text: Pt c/o headache, the began c/o sensitivity to light. On 1/22/09 went to have eyes checked retinas inflamed. Went to ophthalmologist retinas being treated. Then pressure went up, and had surgery on R eye 6/23/09. 7/7/09 Consultant records received DOS 2/4/09 to 6/2/09. Assessment: Retinal vasculitis and vitritis, pars planitis, increased ocular pressure. Patient presents with flashes left eye, black lines. Headaches during day, eyes light sensitive. Floaters right eye. 8/24/09 Received Ophtho medical records of 6/9/09-8/18/09. FINAL DX: Pars planitis right eye; increased intraocular pressure. Patient tx w/diuretic & drops. IOP remained high, developed severe HE.. Surgery of trabeculectomy w/antimetabolites, right eye done 6/23/09. continued to have pain & blurred vision post operatively. Developed heavy feeling in right eye, increased floaters in left eye & hazy vision. 6/30/09 Received PCP & vaccine records of 1/20/2009-2/4/09. Records reveal patient experienced back ache, cervicalgia, HA. Received depo-provera & vaccines. Referred to retina specialist on 2/3 but no office note.

Other Meds:

Lab Data: Many-being treated for last 5 months. Medical records received 7/7/09 LABS: Bartonella benselae (+)

History: 6/30/09 Received medical records PMH: appendectomy, small bowel resection, tonsillectomy. Medical records received 7/7/09 PMH: motor vehicle accident, pleurisy, sulfa allergy

Prex Illness: None

Prex Vax Illns:

Vaers Id: 350416-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		29-Jun-2009	09-Jul-2009	IL		16-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Hypotension, Nausea, Pallor, Syncope, Tremor

Symptom Text: Fainted about 2 - 3min after receiving vaccine with seizure like activity (probably secondary to fainting) pale, nauseous, shaky, low BP. Seemed to recover after 15 min, then fainted again(decrease in BP 84/56) elevated feet another 10-12 minutes, recovered. Took liquids. Walked out OK with mother

Other Meds:

Lab Data: None

History: ADHD; Ocular albinisim

Prex Illness: None

Prex Vax Illns: High fever~DTP (no brand name)~4~2.00~Sibling|Rash~DTP (no brand name)~4~2.00~Sibling

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350426-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	30-Jan-2009	03-Feb-2009	4	29-Jun-2009	09-Jul-2009	AZ		16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Diarrhoea, Vomiting

Symptom Text: Severe abdominal cramping & pain for 48 hours. Severe vomiting & diarrhea for several hours. No specific treatment

Other Meds: YASMIN; ALDAETONE

Lab Data: None

History: Hidradenitis

Prex Illness: None

Prex Vax Illns:

Vaers Id: **350437-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Feb-2008	18-Feb-2008	0	30-Jun-2009	01-Jul-2009	OH	WAES0804USA01051	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a health professional for the Pregnancy Registry for GARDASIL, concerning a 16 year old female with no known medical history or drug reactions/allergies, who on 18-FEB-2008 was vaccinated (route unknown) with a first dose of GARDASIL (Lot # 659655/1486U). There was no concomitant medication. The nurse reports that on 18-FEB-2008 the patient's urine pregnancy test in the office was negative and she received her first dose. The patient returned to the office on 27-FEB-2008 for another urine pregnancy test and a Beta HCG (Human Chorionic Gonadotropin) blood test. Both were positive and showed she was 6 weeks pregnant (LMP 16-JAN-2008). No additional information at this time. The patient sought unspecified medical attention in the office. Outcome unknown. No product quality complaint was involved. Follow up information received on 23-JUN-2009 from a licensed practical nurse stated that the patient delivered at term, by cesarean section for macrosomia, confirmed by the baby's birth weight of 9 LBS, 4 oz. The nurse did not state whether the patient went into labor spontaneously, or was induced. Upon internal review cesarean section for macrosomia was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: urine beta-human, 02/18/08, negat; urine beta-human, 02/27/08, posit, 6 weeks pregnant; serum beta-human, 02/27/08, posit, 6 weeks pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 1/16/2008)

Prex Vax Illns:

Vaers Id: **350438-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Apr-2008	Unknown		30-Jun-2009	01-Jul-2009	MD	WAES0805USA00039	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer for the Pregnancy Registry for GARDASIL concerning her daughter a 14 year old female with no known medical history reported, who on 14-APR-2008 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL (Lot # unknown). On the same day the patient was also vaccinated with a dose of VARIVAX (Lot # unknown) and VAQTA. The caller stated that her daughter received the three vaccines and discovered she was pregnant. At the time of the report the patient was 7 weeks gestation (LMP 12-MAR-2008). No AE reported. The patient had bloodwork and a pelvic exam performed. Outcome unknown. No product quality complaint was involved. Follow up information has been received from a physician, who reported that the 14 year old patient had a termination of her pregnancy soon after her pregnancy diagnosis (date not provided). The termination was not related to having had the GARDASIL vaccine. Upon internal review, termination of pregnancy was considered an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 04/14/08, pregnant; gynecological, 04/14/08, pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 3/12/2008)

Prex Vax Illns:

Vaers Id: **350440-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-May-2009	19-May-2009	5	30-Jun-2009	01-Jul-2009	FR	WAES0906USA04048	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1477U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain lower, Chlamydial infection, Gait disturbance, Muscular weakness, Pain in extremity, Sensory disturbance

Symptom Text: Information has been received from a gynecologist concerning a 16 year old female who on 14-MAY-2009 was vaccinated with the first dose GARDASIL (lot# 1477U, batch NH25390) I.M. into the left deltoid muscle. Concomitant therapy included hormonal contraceptives (unspecified) for systemic use. On 19-MAY-2009, the patient experienced pain in both legs, especially in thighs, sensitivity disorder (not otherwise specified) and weakness of the legs so that she nearly could not walk. On 26-MAY-2009, the patient was admitted to hospital due to hypogastric pain. By clinical investigation a chlamydial infection was detected. Blood sample was taken on an unspecified date results revealed: CRP 0.8 mg/L, hemoglobin 8.4 mmol/l, HK 0.40, Leukocytes 4.79 mmol/l (no normal values available). The patient completely recovered on an unspecified date. Other business partner numbers include E2009-05028. The file was closed. No further information is available.

Other Meds:

Lab Data: WBC count, 4.79 mmol/l; hematocrit, 0.40; hemoglobin, 8.4 mmol/l; serum C-reactive protein, 0.8 mg/L

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350441-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-Apr-2009	23-Apr-2009	0	30-Jun-2009	01-Jul-2009	FR	WAES0906USA04233	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1050U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Asthenia, Headache, Influenza like illness, Pyrexia

Symptom Text: Information has been received from a gynaecologist through the Health Authority under the reference number PEI2009012550 concerning a 21 years old female who on an unspecified date received the first dose of GARDASIL and was well tolerated. On 23-APR-2009, in the morning, the patient was vaccinated with the second dose of GARDASIL (Lot #1050U, Batch # NH32140, injection site and route not reported). Few hours after vaccination, the patient experienced influenza-like symptoms, cephalgia, arthralgia, asthenia and fever up to 39.6 degrees C. She presented herself to hospital and was admitted. Under infusion therapy (liquid substitution) and therapy with antipyretics and analgesics the symptoms resolved and the patient could leave hospital on 24-APR-2009. At the time of reporting, the patient recovered completely. Other business partner numbers included: E2009-05070. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350442-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Mar-2009	04-Apr-2009	25	30-Jun-2009	01-Jul-2009	FR	WAES0906USA04825	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0465U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Optic neuritis, Visual acuity reduced, Visual field defect

Symptom Text: Case reported by health authority (case n. 99935) (local case # IT248/09). Initial report received on 15-JUN-2009. This case is the linked case of a cluster of 2 cases after GARDASIL vaccination, reported by the same physician with the same lot number (0465U) batch number (NG17850). Case linked with case E2009-05042. A 15 year old female was vaccinated with the first dose of GARDASIL (lot number: 0465U, batch number: NG17850) on 10-MAR-2009. The patient referred that on 04-APR-2009, she noticed a difference between the vision of the right eye compared to the left. The ophthalmologist consultation showed reduction of visual field due to optic neuritis. At the time of reporting, the patient had not recovered and she was in therapy NOS with the ophthalmologist. The case was reported as not serious by both the reporter and HA and upgraded to serious by company according to internal rules. Optic neuritis was reported as an other important medical event. Case is closed. No further information is available. Other business partner numbers include E2009-05022.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350443-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Apr-2009	27-Apr-2009	13	30-Jun-2009	01-Jul-2009	FR	WAES0906USA04856	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Condition aggravated, Dizziness, Fall, Hyperhidrosis, Injury, Joint injury, Malaise, No reaction on previous exposure to drug

Symptom Text: Information has been received from a general practitioner concerning a 14 year old female who on 14-APR-2009 was vaccinated with the first dose of GARDASIL (batch # not reported). She was in overweight, was in good health at the moment of vaccination and had already had a few episodes of mild malaises before vaccination. Furthermore, she had problems with the picture of her body in relationship with her age. On an unspecified onset of after vaccination, she presented with mild malaises. To be noted that the patient did not experienced any adverse event immediately after the vaccination. On 27-APR-2009 the patient fell off from a horse and presented with a trauma at the left shoulder. Ever since, she experienced recurrent episodes of malaises associated with stomach pain, sweating, but also sensation of fainting without loss of consciousness, without pain at chest and without neurological deficit. The events would occur when she was at home or at school. Clinical exam of cardiology revealed normal. Glycemia, creatinaemia, cholesterolemia, hepatic work-up, complete blood count, blood iongram, thyroidal work-up and iron work-up all revealed normal. Slight triglyceridemia at 1.52 (normal range inferior to 1.50). Cerebral MRI was normal. Results for Holter ECG and stress test were expected. To be noted that she had well tolerated her previous vaccinations and that there was no particular familial history. At the time of reporting, the outcome was not provided. Malaise and trauma were reported as other important medical events. Additional information has been requested. Other business partner numbers include E2009-05245.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, ??Apr?09, hepatic work- up normal; magnetic resonance imaging, ??Apr?09, cerebral MRI normal; diagnostic laboratory test, ??Apr?09, hepatic work- up normal; diagnostic laboratory test, ??Apr?09, glycemia normal;

History: Malaise

Prex Illness: Overweight

Prex Vax Illns:

Vaers Id: 350444-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		30-Jun-2009	01-Jul-2009	FL	WAES0906USA04964	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Pancreatic mass

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on an unknown date was vaccinated with the first dose of GARDASIL (lot # not reported). On an unspecified date, the patient developed a pancreatic mass after receiving the GARDASIL. The patient was hospitalized and discharged on unknown dates. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350445-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Jun-2009	12-Jun-2009	0	30-Jun-2009	01-Jul-2009	--	WAES0906USA05053	01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction

Symptom Text: Information has been received from a health care worker concerning a 15 year old female patient who on 12-JUN-2009 was vaccinated with the third dose of GARDASIL (Lot # 659054/0315Y). It was reported that on 12-JUN-2009 the patient experienced seizures, immediately following the administration. The patient sought medical attention in the physician's office. It was reported that the patient recovered the same day, 12-JUN-2009. Upon internal review seizures was considered to be another important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350471-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jun-2009	18-Jun-2009	0	30-Jun-2009	09-Jul-2009	PA		15-Jul-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	03154	1	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U2823AA	0	Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB3368AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Muscular weakness, Pain in extremity, Vaccine positive rechallenge

Symptom Text: (LT) upper arm weak & numb x 6 days from deltoid to elbow. Reoccured with Gardasil #2 - (RT) arm, marked pain + weakness - RT upper arm - 5 days (injection sites - ok)

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **350472-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Jun-2009	23-Jun-2009	0	30-Jun-2009	09-Jul-2009	KY		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	2	Right arm	Intramuscular	
	PPV	MERCK & CO. INC.	0625Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Oedema

Symptom Text: PNEUMOVAX given @ 0900 on 6/23/09. At 1530 on 6/23/09, pt. seen in office for increased swelling and erythema to site. Circular edema 5" width, 4 1/2 inches in height - Full ROM. No fever. Please not swelling to left deltoid only, right deltoid with no reaction.

Other Meds: Penicillin, ZOLOFT

Lab Data: pulse oximetry- 100%

History: s/p splenectomy @ 5 yr

Prex Illness:

Prex Vax Illns:

Vaers Id: **350486-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	22-Jun-2009	23-Jun-2009	1	30-Jun-2009	09-Jul-2009	PA		16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Rash generalised, Rash papular

Symptom Text: Generalized red papular rash every- where on body except face and palms.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **350503-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jun-2009	24-Jun-2009	1	30-Jun-2009	09-Jul-2009	OH		09-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2913AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB312AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	03154	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain

Symptom Text: On 6-23-09 received Hep A and MCV-4 in L arm and HPV in R arm. Overnight pain and redness @ injection site. Increased pain and redness on 6-24-09.

Other Meds: GEODON; Clonidine; Lithium; LAMICTAL; NASONEX; Levothyroxine

Lab Data:

History: bipolar; ADHD; Hypothyroid

Prex Illness: anemia; allergic rhinitis

Prex Vax Illns:

Vaers Id: **350543-1 (S)** **Related reports:** 350543-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Oct-2007	01-Nov-2007	10	30-Jun-2009	06-Jul-2009	CA		28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2486AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1063U	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Bedridden, Confusional state, Constipation, Contusion, Diarrhoea, Disturbance in attention, Dizziness, Dyskinesia, Dyspnoea exertional, Eating disorder, Fatigue, Feeling abnormal, Fibromyalgia, Headache, Hypophagia, Hypotension, Loss of consciousness, Menorrhagia, Mental status changes, Migraine, Myalgia, Nausea, Oral contraception, Orthostatic hypotension, Pain, Pain in extremity, Rash, Skin discomfort, Syncope, Vision blurred, Weight decreased

Symptom Text: Faints - blacks out - low blood pressure. Extreme pain in legs and body. Body jerks no concentration brain fog. Rashes, joint pain Fatigue, constipation weight loss - nausea. Headaches bedridden long periods. 7/20/09 Hospital records received DOS 7/18/08 to 7/13/09. Assessment: Orthostatic hypotension and Fibromyalgia. Syncope and Collapse. Migraine. Aversion to eating. Chronic pain syndrome. Multiple ER visits and hospitalizations. Chronic diarrhea and dizzy spells. Decreased PO intake. Weight loss. Headache, blurry vision. Mental status change. Confusion, inability to eat. Uncontrolled pain. Loss of consciousness. On birth control pills. Constipation. 9/4/09 Received ICD9 codes: 4516; 43239; 4580; 7291; 27651; 78701; 78321; 78052; 3384; 56400; 2871. 7/1/09 Medical records received DOS 6/20/07 to 12/24/07 Assessment: Fatigue, arthralgia, myalgia, easy bruising, lack of concentration. Patient presnts with lower leg pain, aching, sore arms, ankle bruising. Heavy menstrual period. Lack of concentration. Allergies. Painful skin with light touch. Constipation, SOB with excercise. Illness at time of immunization: Tired, not sleeping well. Body aches. Stress at school. Sore throat, Amox.

Other Meds: None. Birth control pills.

Lab Data: 7/20/09 Hospital records received DOS 7/18/08 to 7/13/09. LABS and DIAGNOSTICS. Upper GI Series Normal. Abdominal Ultrasound Normal. CBC Normal. Metabolic Panel Normal. MRI/MRA Normal. Cortisol Stimulation Test WNL. Lyme titer - Borderline

History: None. 7/20/09 Hospital records received DOS 7/18/08 to 7/13/09. Fibromyalgia/chronic pain, platelet dysfunction, Lyme disease, orthostatic hypotension. Allergy to Stimate. Head trauma. Leg injury. Irregular menses. 7/1/09 Received medical records w/PMH: Excercise-induced asthma.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **350543-2 (S)** **Related reports:** 350543-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Oct-2007	Unknown		02-Sep-2009	03-Sep-2009	CA	WAES0908USA04104	09-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2486AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1063U		Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Amnesia, Arthralgia, Asthenia, Brain scan normal, Burning sensation, Chest pain, Constipation, Disturbance in attention, Dizziness, Dysuria, Epstein-Barr virus infection, Fatigue, Fibromyalgia, Lyme disease, Migraine, Muscle spasms, Nausea, Pain in extremity, Pruritus, Rash generalised, Scan brain, Somnolence, Speech disorder, Tinnitus, Weight decreased

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter with no medical history or drugs allergies, who on 22-OCT-2007 was vaccinated with a 0.5 mL dose of GARDASIL, intramuscularly. Concomitant therapy included fludrocortisone, ZOFRAN, an unspecified antibiotic, a patch for pain, doxycycline, zaleplon, VALIUM and VICODIN. Forty-eight hours after the vaccination the patient experienced pain in her legs. She also blacks and had dizziness, fatigue, migraines, body spasms, joint pain, weakness, memory loss, difficulty speaking and difficulty concentrating on things. She had loss about 30 pounds because of really bad nausea. When she stands up she gets a real loud ringing in her ears. She had abdominal pain and sensation of burning throughout her body. She had a rash all over her body and she was constantly itching. She gets chest pains. She was constipated and it was really hard for her to urinate. It was hard for her to stay awake. She had been to the emergency room more than 20 times. She was admitted to hospital 3 times. Therapy with GARDASIL was discontinued. All the laboratories tests (unspecified) performed to the patient have come back normal. At the time of this report the patient had not recovered. Follow up information received on 27-AUG-2009 from the physician's office supervisor indicated that the patient was vaccinated with a dose of GARDASIL (lot # 658563/1063U) IM on 22-OCT-2007. Concomitant vaccination given on 22-OCT-2007 included a dose of influenza virus vaccine (lot # U2486AA). The supervisor stated that the patient had not been seen in their office since October 2007. The reporter also indicated that the patient was referred to a rheumatologist. On 28-AUG-2009 information was received from a registered nurse from the office of a pediatric neurologist who reported the following highlights for the patient: the patient has many chronic conditions. She was last seen in their office on 14-APR-2008. Dates for the three hospitalizations were: 19-JUL-2008 to 29-JUL-2008; 10-OCT

Other Meds: VICODIN; antimicrobial (unspecified); VALIUM; doxycycline; fludrocortisone; ZOFRAN; zaleplon

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 350550-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-Jun-2009	29-Jun-2009	0	30-Jun-2009	01-Jul-2009	OK		01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2915AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2774AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0493Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0558X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Crying, Ear pain, Fall, Head injury, Irritability, Nausea, Syncope, Vomiting

Symptom Text: Pt left clinic with mom approx 5 minutes after being seen in clinic ear pain at 2:30 pm and also received four immunizations including HPV (Gardasil), Tdap, Menactra and Varicella. While waiting for valet to bring vehicle, pt told mom she felt nauseous and then fainted and fell backward, hitting her head on the sidewalk. Pt came back to clinic and was upset and crying and had a knot on the upper back portion of her head. The nurse practioner seeing the pt was notified and an RN performed a neuro check which was wnl and ice pack was applied before sending pt to have skull films performed. Pt returned to clinic and was observed for another 30 minutes before releasing to go home with mom. At 2:00 am, mom called triage line because pt was vomiting. Pt was advised to go to ER and did so where a CT Scan was performed which mom reports was WNL so they were sent home.

Other Meds:

Lab Data: Radiology skull films 2 view, CT Scan

History: none noted

Prex Illness: otitis media with rupture of TM

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350553-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-Jun-2009	20-Jun-2009	1	30-Jun-2009	01-Jul-2009	OR		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	00744	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Lymphadenopathy, Oedema, Urticaria

Symptom Text: Erythema, edema, hives, lymphadenopathy, treated with prednisone

Other Meds: acetaminophen

Lab Data:

History:

Prex Illness: Mononucleosis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350555-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jun-2009	30-Jun-2009	0	30-Jun-2009	01-Jul-2009	MI		01-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2842AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dysgeusia, Dyskinesia, Feeling cold, Hyperhidrosis, Immediate post-injection reaction, Pallor, Syncope, Tremor

Symptom Text: fainted immediatley with slight jerking motion. B/P 80/40, pulse 60. Woke a couple seconds later very cold, shaky, 80/50. Very diaphoretic, pale, weak. Client did not eat this AM. Had "bad taste in mouth" Client stayed lying down for 30 minutes before she felt strong enought to stand. Last B/P before leaving was 80/50. Gave her a glass of apple juice.

Other Meds:

Lab Data: none

History:

Prex Illness:

Prex Vax Illns: fainting, vomiting~HPV (Gardasil)~NULL~14~In Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350564-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Jun-2009	30-Jun-2009	0	30-Jun-2009	07-Jul-2009	HI		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294Y	0	Right arm	Intramuscular	HEPA
							TDAP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dizziness, Hypotension

Symptom Text: Pt c/o "dizziness", stomach pain within seconds of administration. Pt closed eyes at this time. Pt placed in supine position with knees raised to chest. BP 90/60. Pt left in position for 5 minutes. Hypotension noted when raised from supine to sitting position, 75/42 taken manually on left arm. Pt placed back in supine position with knees raised x 10 min. BP returned to WNL and pt had no c/o dizziness.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 350565-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Feb-2009	04-Jun-2009	113	30-Jun-2009	07-Jul-2009	WA		07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drooling, Facial palsy, Hypoaesthesia facial

Symptom Text: Inability to close right eye, facial numbness, drooling from right side of mouth Dx: Bells Palsy

Other Meds: none

Lab Data: None

History: none

Prex Illness: Had mild back pain and facial acne. Was seen the following day by orthopedics and had mild scoliosis. RX: follow up only. N

Prex Vax Illns:

Vaers Id: **350566-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jun-2009	30-Jun-2009	0	30-Jun-2009	07-Jul-2009	NY		07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0493Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Patient received Varivax, Gardasil, and PPD. Within in minutes she fainted.

Other Meds:

Lab Data:

History: Narrow QRS Tachycardia. Pt had an ablation 7/08

Prex Illness: None

Prex Vax Illns:

Vaers Id: **350586-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Feb-2008	15-Sep-2008	214	01-Jul-2009	13-Jul-2009	ND		13-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Deafness, Depression, Ear infection, Eye infection, Menstrual disorder, Mood swings, Muscle spasms

Symptom Text: Depression, mood swings, change in menstrual cycle (increase to 2X monthly), cramping, loss of hearing, infection eye + ear.

Other Meds:

Lab Data: CBC; Thyroid tests- negative results reported by mother.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 350603-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	17-Jun-2008	26-Aug-2008	70	01-Jul-2009	02-Jul-2009	--	WAES0810USA00881	06-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug administered at inappropriate site, Drug exposure during pregnancy

Symptom Text: Information has been received from a Certified Medical Assistant (C.M.A.), for the Pregnancy Registry for GARDASIL, concerning a 26 year old female who on 17-JUN-2008 was vaccinated intramuscularly with the first dose of GARDASIL (lot # 659962/1740U) in the left arm and on 22-SEP-2008 was vaccinated intramuscularly with the second dose of GARDASIL (lot # 660620/0571X) in the right hip. Concomitant therapy included hormonal contraceptives (unspecified). The patient became pregnant before the GARDASIL series had been completed. No adverse symptoms. It was reported that the last menstrual period (LMP) was 26-AUG-2008. Medical attention was sought via phone call. No product quality complaint was involved. Follow-up information was received from the nurse practitioner. The nurse reported that the patient had not received any concomitant vaccines when she received the first two doses of GARDASIL. The patient had not received the third dose of GARDASIL. The patient had a miscarriage sometime between August 2008 and December 2008. The patient had recovered from the miscarriage. The patient's last menstrual period (LMP) was also reported as 14-DEC-2008. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 8/26/2008)

Prex Vax Illns:

Vaers Id: 350605-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Apr-2009	08-Apr-2009	0	01-Jul-2009	02-Jul-2009	FR	WAES0906USA05257	06-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Anaphylactic reaction, Bronchospasm, Hypotension, Urticaria

Symptom Text: Information has been received from a health authority (PEI2009012382) concerning a 13 year old female who on 08-APR-2009 was vaccinated with a first dose of GARDASIL (IM, Lot# and injection site not reported). About 2 to 3 hours post vaccination the patient experienced an anaphylactic reaction with urticaria of the entire integument, hypotension and bronchospasm. Under treatment with TAVEGIL 1 ampoule iv, DECORTIN 250mg iv and volume substitution iv. The patient recovered after 2 to 3 hours. The event was assessed as life-threatening by the reporter. Case was closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350630-1** **Related reports:** 350630-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Jul-2009	01-Jul-2009	0	01-Jul-2009	09-Jul-2009	NV		24-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Bradycardia, Cardiac arrest, Dizziness, Lethargy, Loss of consciousness, Pain, Rash, Respiratory arrest, Somnolence, Syncope

Symptom Text: Pt stopped breathing and had a cardiac arrest. CPR required. 7/23/09 Hospital records received DOS 7/1/09 to 7/2/09. Assessment: Syncope vasovagal. Patient dizzy, passed out, loss of consciousness, not breathing spontaneously, CPR initiated. Bradycardia. Presented at ER lethargic and somnolent. Generalized aching severe in nature. Rash on arms. Anemia.

Other Meds: Atarax

Lab Data: 7/23/09 Hospital records received DOS 7/1/09 to 7/2/09. EKG. LABS and DIAGNOSTICS: Troponin I <0.01 NG/ML (L). CAT scan brain - WNL. Echocardiography - trace mitral regurgitation. Carotid Doppler - WNL. CBC - RBC 3.54 M/MM3 (L) Hemoglobin 1

History: Formaldehyde and Quaterium 15 allergies. 7/23/09 Hospital records received DOS 7/1/09 to 7/2/09. Atopic Dermatitis. Loss of consciousness when donating blood.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **350630-2 (S)** **Related reports:** 350630-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Jul-2009	01-Jul-2009	0	02-Jul-2009	07-Jul-2009	NV		15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cough, Dyspnoea, Gaze palsy, Lethargy, Pallor, Pulse absent, Respiratory arrest, Resuscitation, Unresponsive to stimuli

Symptom Text: 10:03 am upon entering room patient became unresponsive and no palp pulse and no breathing. CPR was initiated and after 2nd cycle patient gasped and began breathing and responded appropriately. Once again her eyes rolled back in her head with no breathing or pulse and CPR was again initated and after first cycle she coughed and began breathing and had palp pulse, EKG rate of 42 and then increased to 60's. oxygen was applied at 6 liters per nasal cannula. she was able to give contact information. She remained pale and lethargic but responsive to all questions and responses were appropriate. AMR arrived at 10:20am. Patient evaluated and transported to medical center. ER notified of transport and handoff information given. Patient was lethargic but responsive when she left clinic.

Other Meds: LORATADINE 10MG DAILY, HYDROXYZINE 25MG QID PRN

Lab Data:

History: ATOPIC DERMATITIS, ENVIRONMENTAL ALLERGIES, CONTACT DERMATITIS AND ECZEMA, DOCUMENTED 1+ PATCH TEST TO QUATERNIUM 15 AND FORMALDEHYDE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350639-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jun-2009	01-Jul-2009	15	02-Jul-2009	09-Jul-2009	GU		09-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ26300	0	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Tenderness, Thyroiditis

Symptom Text: SHE WAS GIVEN GARDASIL 1 ST DOSE ON 16/6/2009 AND SHE HAS THYOID SWELLING WHICH IS PATCHY BY DOPPLER CONFIRMATION AND PROBABLY THYROIDITIS WITH TSH AND T3, T4 NORMAL AND ESR ALSO WAS NORMAL, SWELLING IS MILD MILD PAINFUL AND MILD TENDERNESS OVER SWELLING

Other Meds: NO

Lab Data: ESR 17T3 1.5 AND T4 8.75 AND TSH 1.74

History: NO

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **350640-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Jul-2009	01-Jul-2009	0	01-Jul-2009	13-Jul-2009	WA		16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2877AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	AC52B030AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: After giving last injection (which was gardasil) she said she felt like she was going to pass out then slumps into my arms. She opened her eyes again after less than a minute. BP 114/50 cool clothes to head water to drink. Monitored for another 15 mins then sent home.

Other Meds: None

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **350641-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Jun-2009	01-Jul-2009	1	01-Jul-2009	13-Jul-2009	NC		13-Jul-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	AC52B039BA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2908AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB296BA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	04804	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration, Injection site swelling

Symptom Text: 4 cm area of swelling/induration around injection site with associated pruritus.

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350646-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jun-2009	29-Jun-2009	0	02-Jul-2009	13-Jul-2009	MI		13-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Heart rate decreased, Heart rate increased, Immediate post-injection reaction, Loss of consciousness, Memory impairment, Muscle rigidity, Oxygen saturation decreased, Pallor, Unresponsive to stimuli

Symptom Text: Pt was also given T-DAP- MENACTRA, HEP A Pt was given GARASIL (LA), within 30 sec. Pt became pale. unresponsive arms & legs became rigid, lasted for aprox 2 min. After that Pt was pale for aprox 10 min. pulse cx 81 HR 113 pulse cx 91 H.R. 114, pulse cx 73, HR 81, pulse cx 71, HR. 46. B.P. 118/70 4:35 pt. States feeling better - 4:30 ambulance called, pulse cx in 70's H.R. in 40's - B.P. 106/72. Pt no longer pale & able to stand Pt was alert, conscious, coherent GCS (15) when sent to ER. Pt. received total total of 4 shots, #1 T-DAP (LA) #2 GARDASIL #3 HEP A, #4 MENACTRA. Pt states she doesn't remember the 4th shot. When she woke up, she didn't know where she was on the shots. After 10 min she did remember getting shots except for the 4th shot.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **350655-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	29-Jul-2008	Unknown		02-Jul-2009	07-Jul-2009	--		20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Unknown	Intramuscular	HPV4
							MNQ
							TDAP

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia, Neuropathy peripheral, Pain in extremity, Paraesthesia, Sensory loss

Symptom Text: I am unsure if the lateral neuropathy of my daughters left leg is related to the GARDASIL vaccine, but after reading reports of numbness I feel obligated to report the numbness in her left leg. She has seen a neurologist who confirmed the lateral numbness and states there is no cure. 7/7/09 NCS report received DOS 4/8/09. Assessment: Left lateral femoral cutaneous neuropathy. Patient presents with loss of pain and temperature sensation of the left lateral femoral cutaneous nerve. 8/18/09 PCP medical records received DOS 7/21/06 to 4/6/09. Patient presents with leg pain, going numb & "probs' X 3 years. Paresthesias (L) lateral thigh.

Other Meds:

Lab Data: neuro testing 5/2009. 7/7/09 NCS report received DOS 4/8/09. LABS and DIAGNOSTICS: NCS

History: None. 8/18/09 PCP medical records received DOS 7/21/06 to 4/6/09. URI. Contact dermatitis on chin. ADHD.

Prex Illness:

Prex Vax Illns:

Vaers Id: **350660-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jun-2009	30-Jun-2009	0	02-Jul-2009	13-Jul-2009	IL		17-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B039AA	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334AA	0	Left arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBV618AA	3	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Tonic clonic movements

Symptom Text: Immediately following immunization child lost consciousness and experienced tonic-clonic movements of arms, upper body and neck movements. Placed flat and regained consciousness in 20 sec. Color of mucosa remained pink. No resp distress. BP 110/60, HR 88. 911 called- To ER via ambulance, C 12:55 PM.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350663-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	23-Jun-2009	24-Jun-2009	1	02-Jul-2009	13-Jul-2009	NY		20-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Dizziness, Headache, Nausea, Pyrexia, Vomiting

Symptom Text: Dizziness, light headed, fever, nausea, vomiting, joint pain, headache.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350666-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Jul-2009	06-Jul-2009	--	WAES0906USA05296	06-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician concerning his/her daughter's co-worker's daughter who on an unknown date was vaccinated with GARDASIL. It was reported that the patient died after receiving a dose of GARDASIL. The cause of death was not reported. Attempts to verify the existence of an identifiable patient and reporter have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 350668-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	07-Aug-2008	17-Sep-2008	41	02-Jul-2009	06-Jul-2009	FR	WAES0906USA05439	06-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Agranulocytosis, Pyrexia, Thrombocytopenia

Symptom Text: Case received by the health authorities on 26-JUN-2009 under the reference number PS20090584 PS090584. A 22 year old female patient received the first and second dose of GARDASIL 0.5 ml by the intramuscular route respectively on 07-AUG-2008 and 09-SEP-2008 (also reported as 07-SEP-2008). On 17-SEP-2008 she was hospitalized due to a fever associated with agranulocytosis objectivized by the result of a blood count and differential white count. In early September 2008, the patient had taken POLERY per os, DI-ANTALVIC. Dosages and duration were unspecified. Work up performed on 17-AUG-2008 showed leukocytes at 2933 with neutrophils at 29/mm3, and platelets at 137000/mm3. Myelogram revealed an agranulocytosis with blockage of the granular maturation at the promyelocyte level, with no presence of abnormal cells. Virological work up was performed. Results were expected for the following serologies: cytomegalovirus, Epstein Barr virus, HIV, hepatitis B virus, hepatitis C virus, parvovirus B19, HHV6. Infectious mononucleosis serology was negative. The patient was given broad-spectrum antibiotics with TAZOCILLINE and genta. Evolution was marked by an apyrexia and by the increase of leukocytes, neutrophils and platelets rates. Blood count and differential white count on 22-SEP-2008 showed neutrophils at 2830/mm3 and platelets at 254000/mm3. The name of amoxicillin's specialty was not known. To be noted that thrombocytopenia was also coded by the health authorities. At the time of reporting, the patient had recovered. The health authorities assessed the causal relationship between the reported reactions and vaccination as "doubtful" (C2 S1 I1) according to the foreign method of assessment. No further information expected. Other business partner numbers include: E2009-05363.

Other Meds: POLERY ADULTES

Lab Data: bone marrow myelogram, 17Aug08, agranulocytosis with blockage of the granular maturation at the promyelocyte level, with no presence; WBC count, 17Aug08, 2933 /mm3; cytomegalovirus antigen, 17Aug08, results expected; neutrophil count, 17Aug

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 350676-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Jun-2009	01-Jun-2009	0	02-Jul-2009	06-Jul-2009	FR	WAES0906ISR00015	06-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Dizziness, Dysphagia, Face oedema, Hypersensitivity, Lymphadenopathy, Oedema, Paraesthesia, Paraesthesia oral, Pruritus, Rash, Sensory loss, Swelling, Swelling face

Symptom Text: Information has been received from a health professional (a nurse, the patient's mother) concerning a 22 year old female with a history of infectious mononucleosis who on 15-MAR-2009 was vaccinated with GARDASIL first dose. On 01-JUN-2009 the patient was vaccinated with GARDASIL second dose. There was no concomitant medication. On 01-JUN-2009. 6-7 hours post vaccination, the patient experienced weakness, tingling in lips of the injection side, tingling in face of the injection side, tingling in arm of the injection side and loss of feeling in body on the injection side. On 02-JUN-2009 the patient experienced edema and swelling starting at the face and then in the whole body, dizziness and allergic reaction was suspected. The patient was placed on therapy with anti-histamines which was not helpful. The patient experienced dizziness and weakness. On 04-JUN-2009 the patient experienced rash which was first palpable and then visual. The swelling decreased due to therapy with anti-histamines. On approximately 04-JUN-2009, approximately 3-4 days post vaccination, the patient experienced itchiness in arms and legs, swollen and sensitive neck lymph nodes, swallowing difficulty due to the swollen neck lymph nodes. The patient was placed on therapy with Steroids IV. Therapy was not helpful and at this stage the patient was referred to the emergency room. The patient was hospitalized for 3 days. During hospitalization the patient experienced loss of feeling in lips and tongue, itchiness, leukocytes increased and EBV antibodies increased. The patient was placed on therapy with PREDNISONE IV. Subsequently, the patient was released from hospitalization and recovered from tingling in lips of the injection side, tingling in face of the injection side, tingling in arm of the injection side and loss of feeling in body on the injection side, edema and swelling starting at the face and then in the whole body, allergic reaction, rash, itchiness in arms and legs, swollen neck lymph nodes, swallowing difficulty, loss of feeling in lips

Other Meds: None

Lab Data: Epstein-Barr virus antibodies, 04?Jun09, increased; WBC count, 04?Jun09, increased

History: Infectious mononucleosis

Prex Illness:

Prex Vax Illns:

Vaers Id: **350686-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Apr-2009	20-Apr-2009	0	02-Jul-2009	09-Jul-2009	IL		08-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B027AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	2	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthma, Back pain, Chest pain, Dyspnoea, Headache, Painful respiration, Productive cough, Respiratory disorder, Somnolence, Wheezing

Symptom Text: 4/20/09 Later in the day, respiratory problems, chest pain and severe headache-slept all day 4/21/09 and condition worsened. 4/23/09 taken to emergency room. Client say treatment received for respiratory problems. Information reported 6/22/09. 9/1/09 ER records received DOS 4/30/09. Assessment: Asthma. Patient complains of constant pain affecting the anterior chest for 14 days. Pain radiates to back. Productive cough with yellow sputum and chest pain with breathing. Trouble breathing and short of breath. Hurts to cough. Wheezing. ICD9-Codes: 493.90 Asthma type unspecified, 786.2 Cough.

Other Meds:

Lab Data:

History: asthma-no other conditions or allergies. 9/1/09 ER records received DOS 4/30/09. Asthma.

Prex Illness: None per client report

Prex Vax Illns:

Vaers Id: 350704-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jun-2009	23-Jun-2009	22	05-Jul-2009	07-Jul-2009	MD		24-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B028BA	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2408AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0524U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenopia, Blindness, Demyelination, Eye pain, Multiple sclerosis, Optic neuritis, Vision blurred

Symptom Text: The patient received gardisil #1, Tdap and meningococcal conjugate vaccine (ACYW-135) on 01June 2009 -- administered at Pediatrics in facility. On 23June she started having painful and blurred vision in the right eye, she was evaluated by us in the Pediatric Neurology clinic on 26June and found to have right optic neuritis. Brain MRI showed periventricular white matter hyperintensities, one with enhancement. She was admitted for IV steroids. The DDx includes multiple sclerosis vs demyeliation triggered by the immunizations. 7/14/09 MR received for DOS 6/26-28/2009 with D/C DX: Optic Neuritis (R retrobulbar). Pt admitted for IV steroids for 4 day hx of blurry vision, vision loss, eye muscle strain and pain. Neuro consult c/w ON. Will continue to watch for further signs of MS. Tx with IV steroids and d/c on steroid taper.

Other Meds: none

Lab Data: Brain MRI showed periventricular white matter hyperintensities, one with enhancement. Visual acuity in the right eye- 20/60. Labs and Diagnostics: MRI brain (+) demyelinatin lesions suspicious for MS. Visual acuity 20/60 on R, 20/20

History: eczema. PMH: biliary atresia with Kasai procedure, oral surgery

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350706-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	24-Oct-2008	24-Oct-2008	0	02-Jul-2009	13-Jul-2009	PA		13-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Pyrexia

Symptom Text: Pt came for Adagio visit, HPV # 3 due. Pt. states at this time she had reaction to HPV vaccine # 2, and didn't want # 3. Pt. reports she developed fever of 102 within 2 hrs of getting vaccine. Did not contact us at this time. Pt. reports fever getting as high as 103 on Fri afternoon by Sunday was normal. Pt. reports no rash or other symptoms, but felt "sick"

Other Meds:

Lab Data: None; Unable to find documention in EHR to document this, no ED visit

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350708-1** **Related reports:** 350708-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	09-Apr-2009	09-Apr-2009	0	02-Jul-2009	13-Jul-2009	CA		13-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Fatigue, Gastric disorder, Pyrexia

Symptom Text: 6/15/09 Pt. to clinic to receive HPV #2. Pt described symptoms after receiving first GARDASIL IZ within 2 hours after injection experienced fever, gastric distress, fatigued & SOB. Went to ER had to wait 5 hours & was not seen. Symptoms resolved.

Other Meds:

Lab Data:

History: NKDA

Prex Illness:

Prex Vax Illns:

Vaers Id: **350708-2** **Related reports:** 350708-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	09-Apr-2009	09-Apr-2009	0	17-Jul-2009	19-Aug-2009	--	WAES0906USA02095	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Asthenia, Dyspnoea, Pyrexia

Symptom Text: Information has been received from a nurse concerning a 21 year old female patient with no medical history or allergies who on 09-APR-2009 received her first and "only" dose (0.5 ml, IM) of GARDASIL (lot # 661953/1130X). There was no concomitant medication. On 09-APR-2009 after the patient was vaccination with GARDASIL the patient experienced upper gastric pain and shortness of breath. The patient also experienced fever and decreased strength. At the time of this report, the patient had recovered. It was reported that the patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350709-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Jun-2009	17-Jun-2009	0	03-Jul-2009	13-Jul-2009	IL		14-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor

Symptom Text: Pt. received HPV vaccine for 1st time on 6-17-09 at approximately 16:35 as part of P.E. (Pt. had received PPD in other forearm 5 min. prior). At 16:40 pt. in seat & noted to be pale said she would "pass out" & was placed on table. MD called. Vitals assessed. Pt. drank water, rested and walked out of clinic shortly after.

Other Meds:

Lab Data: HR 70 BPM; BP 110/70 -> after event

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 350752-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	16-May-2008	16-May-2008	0	06-Jul-2009	07-Jul-2009	CT	WAES0805USA04794	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abortion induced, Drug exposure during pregnancy, Intra-uterine death, Uterine dilation and curettage

Symptom Text: Information has been received from a 23 years old female for the Pregnancy Registry for GARDASIL who on 16-MAY-2008 was vaccinated intramuscularly with her first dose GARDASIL and found out three days later that she was pregnant. The patient's estimated LMP was 20-APR-2008 and she had a positive pregnancy test. Subsequently the patient experienced no adverse event symptoms and sought unspecified medical attention on an unspecified date by calling the office. Follow up information has been received from the patient who stated that she did get the GARDASIL last year but at 10 weeks in her pregnancy she had a miscarriage. At the time of her receiving the first dose of GARDASIL, she had a negative pregnancy test at the office. After one to two weeks, she performed a home pregnancy test which was positive. She called the physician's office to report it as she was concerned. On her initial prenatal visit, her physical exam was completely normal, and an ultrasound was not routinely done. When she sent to have an ultrasound at the office at 10 weeks, it was found there was no fetal heartbeat. She was asymptomatic. She stated the doctor told her it looked like the fetus had stopped developing about a week or two before that. After the ultrasound, she had some abdominal cramping type pain, but did not spontaneously pass the pregnancy. She "ended up needing a D&C". That went OK, she said, and at her 2 week checkup "everything was fine". Upon internal review, the intra-uterine death and abortion induced were considered as Other Important Medical Events. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic, positive; beta-human chorionic, 05/16/08, negative

History:

Prex Illness: Pregnancy NOS (LMP=4/20/2008)

Prex Vax Illns:

Vaers Id: **350753-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Mar-2008	28-Mar-2008	0	06-Jul-2009	07-Jul-2009	RI	WAES0806USA07772	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breech presentation, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse through the Merck Pregnancy Registry concerning a 16 year old female patient who on 28-MAR-2008 was vaccinated with the first dose of GARDASIL. On 22-MAY-2008 the patient was vaccinated with the second dose of GARDASIL. There was no concomitant medication. The patient was pregnant. The patient has not experienced any know symptoms. The patient sought medical attention seen by the physician. Follow-up information was received from a health professional. The patient delivered on 05-DEC-2008 via C-section due to breech presentation. The baby was 6 lb 5 oz and completely normal and healthy with no congenital anomalies. Upon internal review, C-section due to breech presentation were determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 3/28/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350754-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Aug-2008	18-Aug-2008	0	06-Jul-2009	07-Jul-2009	--	WAES0812USA02378	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal disorder, Poor weight gain neonatal, Premature labour

Symptom Text: Initial and follow-up information has been received from a Nurse Practitioner for the pregnancy registry for GARDASIL From a nurse practitioner concerning a 16 year old female patient with a history of no previous pregnancies who on 18-AUG-2008 was vaccinated with a 0.5 mL second dose of GARDASIL (LOT # 659964/1878U) while she was pregnant. The estimated conception date is 01-JUL-2008 and the estimated delivery date is 24-MAR-2009. The nurse reported that on 18-JUN-2008 the patient received a 0.5 mL first dose of GARDASIL (LOT # 659653/1448U). A healthcare worker in the Nurse Practitioner's office reported that the patient had no prenatal care until she was 5 months along. She delivered her baby 2 months premature. The baby had reflux issues and slow weight gain. Her neurological status was within normal limits. She did confirm that there were no congenital anomalies and the baby was, otherwise, normal. Upon internal review, premature was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 6/17/2008)

Prex Vax Illns:

Vaers Id: **350755-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-May-2009	20-May-2009	0	06-Jul-2009	07-Jul-2009	FR	WAES0906USA04237	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Hypotonia, Loss of consciousness, Presyncope

Symptom Text: Information has been received from Health Authority (HA, reference number ES-AGEMED-118812447) concerning a 12 year old female who on 20-MAY-2009 was vaccinated with GARDASIL by intramuscular route (site of administration not reported). It was reported after vaccine administration the patient presented loss of consciousness and convulsion of short duration, and sphincter relaxation. The patient recovered from loss of consciousness shortly after. HA have coded vasovagal reaction, convulsion and loss of consciousness. According to the report, patient recovered from vasovagal reaction, convulsion and loss of consciousness on 20-MAY-2009. Outcome of sphincter relaxation has not been reported. No further information reported. Case reported as serious by Health Authority with other important condition as criteria. Case is closed. Other business partner numbers included E2009-05161. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350756-1** **Related reports:** 350756-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	09-Jun-2009	13-Jun-2009	4	06-Jul-2009	07-Jul-2009	NY	WAES0906USA04956	05-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Hemiparesis, Pain, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 22 year old female with no pertinent medical history who on 06-APR-2009 was vaccinated with the first dose of GARDASIL (lot # 661953/1130X) and on 09-JUN-2009 received a second dose of GARDASIL (lot # 662404/0312Y) in her left arm. Concomitant therapy included birth control (unspecified). There were no concomitant vaccinations administered with the GARDASIL. On 13-JUN-2009, the patient had motor weakness. She started experienced tingling on her face, left arm, hand, leg and foot. It then progressed to pain and tingling on the entire left side of her body. The patient is left handed. The patient was able to work. The physician reported that the patient was seen by a neurologist who did a magnetic resonance imaging and a magnetic resonance angiography on the patient and the results came back normal. The physician indicated that the patient had not recovered, and the patient had been monitored every day and she could not go on vacation. The patient sought medical attention with her physician. Follow up call information from the neurologist indicated that the patient had left-sided weakness. The patient's magnetic resonance imaging and magnetic resonance angiography were normal. The neurologist stated that as of 29-JUN-2009, there was no definitive diagnosis. The patient would have a repeat magnetic resonance imaging for the next week. Upon internal review, left-sided weakness was determined to be an other important medical event. Additional information has been requested. ```Neurology consult records received 3/4/2010. Service date 7/9/09. Imaging studies only. Assessment: Suggestive of demyelinating disorder.

Other Meds: Unknown

Lab Data: Magnetic resonance, normal; Vascular imaging, normal. ```LABS and DIAGNOSTICS: MRI Cervical Spine - Abnormal. MRI Brain w/wo Gadolinium - Abnormal.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **350756-2** **Related reports:** 350756-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	09-Jun-2009	14-Jun-2009	5	17-Aug-2009	27-Aug-2009	NY		27-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Inflammation, Sensory loss

Symptom Text: I received my second dose of the gardasil (HPV) vaccine on 6/9/09. Six days later I woke up and my left arm was numb. The loss of sensation persisted, and three days after that the entire left side of my body (face, neck, chest, torso, arm, leg, hand) lost sensation. I began to have a shock sensation when I put my head down to my chest. I saw a neurologist who sent me to the emergency room for x-rays. It turned out that my cervical spine was inflamed. It is now two months later, and I am finally starting to get sensation back on the left side of my body. I was 100% healthy before going in for this vaccine.

Other Meds: Yaz

Lab Data: MRI of brain and cervical spine, test for lyme disease.

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 350757-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		06-Jul-2009	07-Jul-2009	--	WAES0906USA05043	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contraception, Convulsion

Symptom Text: Information has been received from a physician assistant concerning a 15 year old female who on an unspecified date was vaccinated with the first 0.5ml dose of GARDASIL (IM, lot number unspecified). Originally the patient's pediatrician sent the patient to the physician assistant to have DEPO-PROVERA inserted (on an unspecified date). The patient went back to her pediatrician (on an unspecified date) and received the first dose of GARDASIL. The GARDASIL vaccine and DEPO-PROVERA administration were started "around the same time". It is reported that the information for DEPO-PROVERA stated that seizures had been associated with it. Approximately 4 weeks after administration she developed seizures. An electroencephalography (EEG) was performed and the technician performing the test asked the patient's mother if the patient have had a head injury so the physician assistant thought there might have been some "activity" showing up (not further specified). The patient had not received any further doses of GARDASIL and the DEPO-PROVERA had been removed. At the time of the report, the patient's status was unknown. Upon internal review, seizures was determined to be an other important medical event. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: electroencephalography, some "activity"

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 350758-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Jul-2007	01-Jul-2008	366	06-Jul-2009	07-Jul-2009	PA	WAES0906USA05205	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Colectomy total, Colitis ulcerative, Condition aggravated, Inappropriate schedule of drug administration, Surgery

Symptom Text: Information has been received from a physician and her office manager concerning a 19 years old female with no drug reactions and a history of anemia and ulcerative colitis which began at age 17 years who in July 2007, was vaccinated with the first dose of GARDASIL. In July 2008, the patient had a Total Colectomy and was hospitalized. In October 2008, the patient had J-Pouch surgery and on 05-JAN-2009, had "reversal" surgery. On 25-JUN-2009 (also reported as April 2008), the patient was seen in physician's office and received the second dose of GARDASIL (lot # 660616/0570X). At the time of reporting, the patient had recovered. Total Colectomy, J-Pouch surgery and "reversal" surgery were considered to be other important medical events, disabling and life-threatening. Follow up telephone call was made to the physician, and was transferred to the Office Manager. The Office Manager was not able to confirm that the patient's surgeries (Total Colectomy, J-Pouch surgery and reversal surgery) were related to a worsening of ulcerative colitis. Additional information has been requested. 7/7/09 Spoke with mother-emphatically denied that symptoms were related to HPV4, patient has a long history of colitis and does not want any follow-up on this report.

Other Meds: Unknown

Lab Data: Unknown

History: Anaemia; Colitis ulcerative

Prex Illness:

Prex Vax Illns:

Vaers Id: **350759-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Jun-2008	11-Jun-2008	0	06-Jul-2009	07-Jul-2009	KY	WAES0906USA05705	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with seasonal allergies who on 11-JUN-2008 was vaccinated with the first dose of GARDASIL (Lot number 659653/1448U) 0.5 mL intramuscular in the right arm. On 11-JUN-2008, the patient fainted after her initial GARDASIL, she reportedly fainted in the office with "seizures like movements", then became responsive immediately after. The patient sought medical attention in the office and was sent to the emergency room (name unspecified) but was not admitted. The patient did not continue with the series. Seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

Vaers Id: 350760-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Oct-2008	Unknown		06-Jul-2009	07-Jul-2009	FR	WAES0906USA05734	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1526U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Bite, Computerised tomogram normal, Convulsion, Face injury, Grand mal convulsion, Loss of consciousness, Malaise, Nausea, Tetany, Vaccine positive rechallenge, Vomiting

Symptom Text: Case received from a general practitioner on 25-JUN-2009 and transmitted through a sales representative. A 16 year old female patient with no post-vaccinal or epilepsy history neither for her or her family received the first dose of GARDASIL (lot # 1526U, batch # NH38010) via intramuscular route in the deltoid on 09-OCT-2008. One month after vaccination, during a familial party (without sound and lights) the patient lay dawn and had a true loss of consciousness during 15 minutes. She also bit her cheeks. When she woke up, she did not remember the evening nor the malaise. There was no loss of urine. At the emergency care department, tetany crisis was diagnosed. Head computed axial tomography scanner was normal. As no electroencephalogram was performed, the diagnosis was incorrect according to the reporter. She received the second dose of GARDASIL (lot # 1883U, batch # NH50490) via intramuscular route in the deltoid on 04-DEC-2008. On 26-DEC-2008, i.e. after Christmas eve, 22 days after vaccination, at approximately 2:00 am, the patient woke up as she was feeling unwell. She presented with nausea and vomiting. She took a shower and experienced a malaise with loss of consciousness and convulsive crisis. There was no loss urine. Electroencephalogram was performed on 30-DEC-2008. First diagnosis was juvenile myoclonic epilepsy. But eventually final diagnosis was idiopathic generalized epilepsy. The third dose was not administered. The patient was given KEPPRA but badly tolerated it. The treatment was changed to LAMICTAL, which was ongoing at the time of reporting. There was no new crisis since the one experienced in December 2008. Electroencephalogram was regulatory performed. At the time of reporting, the outcome was not specified. Generalized convulsive epilepsy and feeling unwell were considered to be other important medical event. Other business partner numbers include E2009-05417. No further information is available.

Other Meds: Unknown

Lab Data: electroencephalography, 30Dec08, Final diagnosis was idiopathic generalized epilepsy

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 350761-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Apr-2008	20-Mar-2009	340	06-Jul-2009	07-Jul-2009	FR	WAES0906USA05735	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dysstasia, Fatigue, Infective myositis, Influenza like illness, Myalgia, Sensation of heaviness

Symptom Text: Case received from a general practitioner on 24-JUN-2009: A 17-year old female patient who had received the first dose of GARDASIL (lot # and batch #) on 14-APR-2008 received and the second dose of GARDASIL (lot # and batch #) on unspecified date in February 2009. One month after vaccination, she presented with muscle pain, fatigue, heaviness in the legs and she could not stand up anymore once seated. She was hospitalized approximately on 20-MAR-2009. Creatine Kinase was at 32000 and C-Reactive Protein at 43. Infective myositis was diagnosed as the patient had also experienced influenza-like syndrome a few days before these events. At the time of reporting, the patient was doing better but creatine kinase was still high (value not reported). No serology was performed. The performing of muscular biopsy was under discussion. The outcome was not specified. Other business partner numbers include E2009-05430. No further information is available.

Other Meds: Unknown

Lab Data: serum C-reactive protein, 43; serum creatine kinase, 32000

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350762-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		06-Jul-2009	07-Jul-2009	FR	WAES0906USA05744	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Haemorrhagic cyst, Ovarian disorder, Pelvic pain

Symptom Text: Information has been received from a gynaecologist concerning a 15 year old female with irregular menstrual cycle who was virgin and who did not take any contraception who was vaccinated with second dose of GARDASIL (batch number not reported) on an unspecified date. 48 hours after vaccination, the patient presented to the Emergency Unit Care. The reporter did not know whether she was kept at the hospital for the night. An ultrasound revealed a mild ovarian dystrophia. The gynaecologist had a doubt regarding the hemorrhagic cyst. To be noted that the painful syndrome had started during her menstrual cycle. The patient had already experienced abdominopelvic pain 48 hours after receiving the first dose of GARDASIL (date unspecified). She was given analgesics and SPASFON as corrective treatment. At the time of reporting, the patient had recovered from abdominopelvic pain but the final outcome was not provided. Other business partner numbers included: E2009-5441. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, Mild ovarian dystrophia

History:

Prex Illness: Irregular menstrual cycle; Not sexually active

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350770-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-May-2009	14-May-2009	0	06-Jul-2009	07-Jul-2009	FR	WAES0906USA05259	07-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-006470348) regarding an 11 year old female who on 14-MAY-2009 was vaccinated with the third dose of GARDASIL (batch number not reported) by intramuscular route (site of administration not reported). It is reported that after vaccine administration the patient suffered a syncope with loss of consciousness, the patient recovered after several minutes. Case reported as serious by the HA with other medically important condition as criteria. Case is closed. Other business partner numbers include E2009-05318.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350778-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Jul-2009	06-Jul-2009	0	06-Jul-2009	15-Jul-2009	IL		15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2664AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3031BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Immediate post-injection reaction, Loss of consciousness, Pallor, Syncope

Symptom Text: Fainted after recieving immunizations.Turned pale. Fell to the floor. Patient passed out for 10 seconds. Stated that she felt dizzy when she came to.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **350780-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Jul-2009	06-Jul-2009	0	06-Jul-2009	15-Jul-2009	IL		15-Jul-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B036BA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2664AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0558X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Muscular weakness

Symptom Text: Patient recieved shots, walked out of room feeling fine. Walked over to the check out desk after standing there for a few seconds knees gave out and started to fall. Patient lowered to the floor, did not pass out completely.Patient had not eaten yet today. Responded to questons. Was given some orange juice. Left office 15 min later feeling better.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **350793-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jun-2009	30-Jun-2009	0	06-Jul-2009	16-Jul-2009	KY		17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1317X	1	Unknown	Subcutaneously	
	MNQ	SANOFI PASTEUR	U266AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Local reaction, Oedema peripheral, Pain in extremity, Urticaria

Symptom Text: 14 yr old fe here today with Aunt (who has legal custody of child.) to show nurse Rt arm - Local reaction back of Rt arm red, raised, swollen area measures 10" x 11" has a red raised center approx 2" sore to touch - Arm started to swelling some that night after the injection - Had VARIVAX AND GARDASIL #1 same arm - MENINGITIS vaccine

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 350817-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Jun-2008	20-Jun-2009	365	06-Jul-2009	13-Jul-2009	NJ		16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2404AA	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2638AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Brain injury, Cardiac operation, Dystonia, Encephalopathy, Expressive language disorder, Gastrointestinal tube insertion, Hemiparesis, Injection site erythema, Injection site induration, Injection site swelling, Pancreatitis, Pharyngitis

Symptom Text: GARDASIL. Redness, swelling area hard around vaccine. Had open heart surgery 6/27/09. Suffered brain injury. Lactic acids raised to brain, abnormal white matter. 7/13/2009 MR received from PCP 6/20-/2009. In for WCC on 6/20/09. For surgical repair of ASD in 1 week. Impression: Healthy. ASD. Returned 6/23/09 to have throat checked. Impression: Pharyngitis. In for surgury ~6/27/09 with "catastrophic event" intraoperatively with subsequent encephalopathy. ? Mitochondrial defect. Pt currently with L hemiparesis, R dystonia, non-verbal with receptive language intact. S/P pancreatitis with G-tube feeds. Transferred to higher level of care.

Other Meds: None

Lab Data: Lost all metabolic ability.

History: ASD

Prex Illness: Hole in heart

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350835-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	16-Apr-2009	16-Apr-2009	0	25-Jun-2009	29-Jul-2009	FR	2009020094	13-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	CSL LIMITED	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Similar reaction on previous exposure to drug, Syncope

Symptom Text: Report received from a nurse on 16-APR-2009. A female patient aged in her 20's (Initials: unknown, Date of Birth: unknown) received FLUVAX and GARDASIL on 16-APR-2009. Batch numbers are unknown. The patient has a relevant medical history of nausea and fainting with previous vaccine administrations. It is unknown whether the patient was taking any concomitant medications. On 16-APR-2009 after both FLUVAX and GARDASIL were administered, the patient developed fainting and nausea. The patient had to lie down for approximately 1 hour. The patient recovered after 1 hour and after eating something. No other treatment was administered. The reporter considered events as non-serious and unlikely related to the administration of FLUVAX and GARDASIL. The company considered event causality as unassessable in relation to the administration of FLUVAX as it is unknown whether the patient was taking concomitant medication and it is known that GARDASIL was administered on the same day. Information derived from this AE does not change the current safety profile of the product.

Other Meds: None

Lab Data:

History: Nausea with previous vaccine administration; Fainting with previous vaccine administration

Prex Illness:

Prex Vax Illns:

Vaers Id: 350857-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	04-Feb-2008	21-May-2008	107	07-Jul-2009	08-Jul-2009	PA	WAES0807USA03163	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a 24 year old female, for the Pregnancy Registry for GARDASIL, concerning the 24 year old female who in December 2007, was vaccinated intramuscularly with the first dose of GARDASIL and in June 2008, was vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL. There was no concomitant medication. The patient was two weeks pregnant while receiving the third dose of GARDASIL. The pregnancy test was positive. Unspecified medical attention was sought. Follow-up information on 01-JUL-2009 was received from an other healthy professional who reported that the patient with a history of 1 pregnancy and 1 live birth was vaccinated intramuscularly with the first dose of GARDASIL on 03-DEC-2007, on 04-FEB-2008, was vaccinated intramuscularly with the second dose of GARDASIL vaccine (lot # 655327/1287U) and on 04-JUN-2008, was vaccinated intramuscularly with the third dose of GARDASIL (lot # 655604/0052X). On 23-SEP-2008, ultrasound was performed with normal result. On 15-OCT-2008, maternal serum alpha-fetoprotein (MSAFP) was performed with negative result. On 13-FEB-2009 (Weeks from LMP: 39), the patient delivered a male infant with congenital anomaly cleft palate, weight: 8 lbs 3 oz and Apgar score 8/9. As of 01-JUL-2009, the outcome of cleft palate was unknown. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, 09/23/08, normal, routine anatomy scan; beta-human chorionic, positive; serum alpha-fetoprotein, 10/15/08, negative; Apgar score, 02/13/09, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 5/23/2008)

Prex Vax Illns:

Vaers Id: **350858-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Sep-2008	Unknown		07-Jul-2009	08-Jul-2009	PA	WAES0906USA05239	13-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB264A	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Cough, Eye oedema, Eye swelling, Inappropriate schedule of drug administration, Malaise, Nausea, Vaccine positive rechallenge, Wheezing

Symptom Text: Initial information has been received from a physician concerning a 14 year old female patient who received the second dose of GARDASIL and experienced "swelling and edema of the eye" and saw treatment at ER where she was given BENADRYL. The physician stated that she had the same experience after the first dose. The patient was due for her third dose in about a week and she was planning on receiving it. The swelling resolved after about a week, the patient had recovered. Follow up information has been received from a registered nurse concerning the 15 year old (initial reported as 14 year old) female patient who on 04-SEP-2008 was vaccinated with the first dose of GARDASIL (Lot # 0250X) and concomitantly received the second dose of HAVRIX (Lot # AHAVB264A). On 02-JAN-2009, the patient received the second dose of GARDASIL (lot# 0947X). On 24-Jun-2009, the patient was seen by the physician with complaints of a cough and wheezing. At the time of the physician's visit the patient's father stated that after the patient had received the first dose of GARDASIL, the patient was ill and nauseous and missed 1 week of school. The patient also had swelling and edema of both eyes. After the patient received the second dose of GARDASIL, the patient had swelling and edema of both eyes. The patient went to the Emergency Room and was treated with BENADRYL (route unknown to the reporter). The patient was not admitted to the hospital. The registered nurse stated that the patient was scheduled to receive the third dose of GARDASIL on 29-JUN-2009. The registered nurse requested to speak with a Merck physician prior to administering the third dose of GARDASIL to the patient. Follow up information has been received from a memo indicated that a Merck physician had spoken to the registered nurse. They have decided to not administer the third dose on 29-JUN-2009. Missing 1 week of school was considered to be disabling by the physician. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350859-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		07-Jul-2009	08-Jul-2009	--	WAES0906USA05566	08-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervix carcinoma

Symptom Text: Information has been received from a female patient who on an unknown date was vaccinated with GARDASIL. "15 months from the completion of the GARDASIL vaccination" the patient had full blown cervical cancer. The patient's oncologist would like to do a hysterectomy at this time, but the patient stated that she always wanted children. The patient had chosen to wait. The patient stated that she had two of the strains that the shot was supposed to prevent. At the time of reporting the patient had cervical cancer. The outcome of the patient's cervical cancer was not reported. Upon internal review the patient's cervical cancer was considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 350860-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	04-Jun-2007	18-Mar-2008	288	07-Jul-2009	08-Jul-2009	VA	WAES0906USA05633	08-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Hypertension

Symptom Text: Information has been received from a licensed practical nurse, for GARDASIL, a pregnancy registry product, concerning a 24 years old female patient with no medical history and no allergies who on 09-APR-2007 was vaccinated IM with the first 0.5ml dose of GARDASIL (lot # 657005/0314U). The patient received IM the second 0.5ml dose of GARDASIL on 04-JUN-2007 (lot # 657002/0337U, which belongs to VARIVAX). There was no concomitant medication. On 29-JUN-2009, the patient received the third dose of GARDASIL (lot # 661841/0653x). The patient did not receive any concomitant vaccinations when the three doses of GARDASIL were administered. After the patient was administered her second dose of GARDASIL she was determined to be pregnant. The patient required an unscheduled c-section on 18-MAR-2008 due to hypertension. The infant was a normal, full term baby with no complications. At the time of this report, the patient had recovered. It was reported that the patient sought unspecified medical attention. Upon internal review, the unscheduled c-section due to hypertension was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 350861-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Mar-2009	19-Mar-2009	0	07-Jul-2009	08-Jul-2009	FR	WAES0906USA05746	08-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Chest pain, Costochondritis, Dyspnoea, Hyperventilation, Musculoskeletal pain, Oedema peripheral, Syncope, Tremor

Symptom Text: Information has been received from a health authority under reference 2009-02416 concerning a 15 year old female adolescent who received on 19-MAR-2009 one intramuscular dose of GARDASIL (batch # and site of administration not reported). After 30 minutes swelled the hand of the injected arm. After another hour the swelling was decreasing again and formed back. On the 20-MAR-2009, she developed chest pain substernal, dyspnea and syncope. After a few of hours, she recovered. In April 2009, occurred articular and musculoskeletal pains and irregular trembling of the left leg and right arm. In the end of May, the patient reported a slow improvement in these adverse events. In the meantime, investigations carried out revealed a diffuse pressure the long joints and the muscle without clinical arthritis signs. The neurological complaints seemingly not correlate with an objective pathology. In the neurological examination, the suspects asked a TIETZES syndrome with intermittent hyperventilation-related breathing disorder as a timer for circulatory collapse and sterno thoracic pain. On 18-MAY-2009 a borrelienserology was negative for IgM and IgG after questionable findings on 21-APR-2009 was positive. Upper limb oedema, arthralgia, chest pain substernal, dyspnea, musculoskeletal pain, syncope and tremor were considered other important medical events per physician. Other business partner number included: E2009-05237. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 18May09, borrelienserology: negative for IgM and IgG

History: Circulatory collapse

Prex Illness:

Prex Vax Illns:

Vaers Id: **350862-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	01-Mar-2008		07-Jul-2009	08-Jul-2009	--	WAES0906USA05780	08-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Alopecia, Contusion, Convulsion, Gingival bleeding, Headache, Pain, Tremor

Symptom Text: It was reported in a newspaper article that an 18 year old female who was vaccinated with GARDASIL (dose, route and lot numbers unspecified). On an unspecified date after the patient received the vaccine, she began having seizures in the spring 2008 (approximately March 2008), often more than once a day. Her body, her brain, her stomach ache, her hair fell out, her gums bleed, her legs bruise, her hands shake with tremors. The patient "didn't die, but there are days when death seems to hover nearby". At the time of the report, the outcome of the patient was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 350863-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.3	F	Unknown	01-Feb-2009		07-Jul-2009	08-Jul-2009	TX	WAES0907USA00186	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anxiety, Burning sensation, Dementia, Grunting, Hallucination, Heart rate increased, Hyperhidrosis, Hyperventilation, Insomnia, Panic attack, Tic, Weight decreased

Symptom Text: Information has been received from a physician concerning a female patient with asthma who on an unknown date, was vaccinated with the first dose of GARDASIL. Concomitant therapy included MAXAIR. A couple of days later after receiving GARDASIL, the patient started presenting with anxiety, dementia, panic attacks, loss of sleep, weight loss, hallucinations and hyperventilation. The patient was put on antidepressants (unspecified) and her symptoms got worse and she was taken to the ER on 02-FEB-2009. After the antidepressants the patient experienced burning, sweating, tics, rapid heart beat and vocal grunt and was admitted to the psychiatric hospital. The patient will not receive further doses of GARDASIL. The patient was released since she was feeling a little better and started eating, however she is showing early signs of dementia. The patient's adverse experiences were considered to be disabling. Additional information has been requested.

Other Meds: MAXAIR

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **350870-1 (S)** **Related reports:** 350870-2; 350870-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jun-2009	25-Jun-2009	1	07-Jul-2009	13-Jul-2009	WI		07-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	3	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Areflexia, Asthenia, Clonus, Constipation, Extensor plantar response, Hypertension, Hypoaesthesia, Insomnia, Joint range of motion decreased, Muscular weakness, Musculoskeletal stiffness, Myelitis transverse, Neck pain, Paraesthesia, Reflex test abnormal, Temperature perception test abnormal, Tremor, Urinary retention, Venom poisoning, Vibration test abnormal

Symptom Text: Pt had 3rd GARDASIL Injection and was diagnosed with transverse myelitis and is being treated with steroids. Pt has LE weakness. 7/17/09 Medical records received DOS 6/25/09. Assessment: Skin sensation disturb, toxic effect venom, cervicalgia. Patient presents with entire left side numb, neck pain and trunk area tingling X 3 days. Not able to sleep because of neck pain, paresthesias. Decreased ROM of cervical spine. 7/23/09 Hospital records received DOS 6/30/09. Diagnosis: tranverse myelitis, hypertension, anxiety, constipation, urinary retention. Patient presented with worsening neck pain and weakness below the waist. Numbness left side of neck, shoulder, arm. Babinski (+) No patellar reflex on right. Tremor in hands. Weakness, paresthesias, brisk tendon reflexes, clonus ankles, alterations in temperature and vibration sense. Neck stiffness.

Other Meds: DEPO-PROVERA

Lab Data: 7/17/09 Medical records received DOS 6/25/09. LABS and DIAGNOSTICS: Monofilament feels different on left. CBC - Lymphocytes 18% (L). TSH - WNL. Vitamin B12 - WNL. 7/23/09 Hospital records received DOS 6/30/09. LABS and DIAGNOSTICS: Urin

History: Bee stings. 7/23/09 Hospital records received DOS 6/30/09. Gravida 1, para 0. Chickenpox. Wheezing as a toddler. Smokes. Alcohol. Marijuana. Allergy to a venom.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **350870-2 (S)** **Related reports:** 350870-1; 350870-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	24-Jun-2009	30-Jun-2009	6	27-Jul-2009	28-Jul-2009	--	WAES0907USA03605	07-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	3	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Asthenia, Clonus, Constipation, Diplegia, Extensor plantar response, Hyperreflexia, Hypertension, Hypoaesthesia, Musculoskeletal stiffness, Myelitis, Neck pain, Paraesthesia, Reflex test abnormal, Sensory disturbance, Tremor, Urinary retention

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female with a "history of illicit drug use" who on 24-JUN-2009 was vaccinated IM with her third 0.5mL dose of GARDASIL. On 30-JUN-2009, the patient "went to the ER (hospital unspecified) with numbness and paralysis in her lower limbs" and was hospitalized. At the time of reporting the patient had not recovered from paralysis and numbness. It was noted that there were no adverse events with the first two doses. Additional information has been requested. 10/23/09 Hospital records received DOS 6/30/09. Diagnosis: tranverse myelitis, hypertension, anxiety, constipation, urinary retention. Patient presented with worsening neck pain and weakness below the waist. Numbness left side of neck, shoulder, arm. Babinski (+) No patellar reflex on right. Tremor in hands. Weakness, paresthesias, brisk tendon reflexes, clonus ankles, alterations in temperature and vibration sense. Neck stiffness. 10/21/09 Vaccine records received. No changes to VAERS

Other Meds: Unknown

Lab Data: Unknown. LABS and DIAGNOSTICS: Urine Drug Screen Positive for benzodiazepines and opiates. Chest X-ray - WNL. X-ray Cervical Spine - Mild reversal of cervical lordosis. X-ray Thoracic Spine - chronic degenerative disc disease. MRI Thoracic

History: Drug abuse. Gravida 1, para 0. Chickenpox. Wheezing as a toddler. Smokes. Alcohol. Marijuana. Allergy to a venom.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350875-2** **Related reports:** 350875-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jun-2009	24-Jun-2009	0	17-Jul-2009	19-Aug-2009	NY	WAES0906USA05365	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain

Symptom Text: Information has been received from a nurse concerning a 17 year old female who on 24-JUN-2009 was vaccinated with the third dose of GARDASIL (0.5ml, intramuscular administration, lot# and site of administration not reported). Subsequently the patient experienced redness and soreness around the injection site. Unspecified medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350877-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Jun-2009	29-Jun-2009	0	07-Jul-2009	16-Jul-2009	VA		16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2G85AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Dizziness, Loss of consciousness, Pallor

Symptom Text: Pt. Was given 1st GARDASIL shot today. Pt. passed out after feeling faint and sick to stomach. Pt. was pale but opened eyes and was alert after Ammonia salts.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **350886-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.5	F	23-Jun-2009	24-Jun-2009	1	07-Jul-2009	16-Jul-2009	PA		16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334CA	1	Right leg	Intramuscular	
	VARCEL	MERCK & CO. INC.	0045Y	1	Right leg	Subcutaneously	
	HPV4	MERCK & CO. INC.	065X	1	Left leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Erythema, Oedema peripheral, Pain, Pain in extremity, Skin warm

Symptom Text: 6/24/09 redness, swelling, warmth, soreness below sight of varicella immu Dx "Mild Superficial Cellulitis". Rx KEFLEX 500 mg po BID x 10d. 6/25/09 increased redness c/o painful thigh no streaking. Rx ROCEPHIN 1 Gm L buttocks D/C KEFLEX CBC WNL. 6/26/09 leg looking much better she is feeling better.

Other Meds: None

Lab Data: Mild Superficial Cellulitis; CBC WNL

History: Allergic Amoxicillin

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350897-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Jun-2009	30-Jun-2009	1	07-Jul-2009	16-Jul-2009	NY		16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Patient received HPV #2 @ 4 pm 6/29/09. Developed generalized urticarial rash 6/30/09 @ 8 pm.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350931-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Jul-2009	03-Jul-2009	2	07-Jul-2009	16-Jul-2009	IA		16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB350AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0658Y	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Injury, Loss of consciousness, Muscle twitching, Paraesthesia, Rash, Swelling face, Syncope

Symptom Text: 7/01/2009 Dr. reported that patient had syncope x 2, tiredness, dizziness, swollen/rash on face on 7/1/09 at 1630. Pt. passed out and injured self. Dr. reported left leg paresthesia and twitching.

Other Meds: NONE

Lab Data: Unknown

History: UNKNOWN

Prex Illness: UNKNOWN

Prex Vax Illns:

Vaers Id: **350938-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-May-2009	07-May-2009	6	07-Jul-2009	16-Jul-2009	CT		16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0000	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: The injection was given on May 1, 2009. Approximately 1 week after receiving the patient's third injection, the patient developed small warts on her hands and fingertips. As of today, July 7, 2009 The warts are still existant.

Other Meds: Yasmin 28

Lab Data:

History: Allergic to Penicillin, Suprax, Biaxin. Patient has Pre-existing Asthma and Psoraisis.

Prex Illness: None

Prex Vax Illns: Warts on Hands and Fingers~HPV (Gardasil)~2~20~In Patient

Vaers Id: 350945-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Mar-2009	07-Jul-2009	98	08-Jul-2009	16-Jul-2009	CA		26-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Chest pain, Confusional state, Dyskinesia, Grand mal convulsion, Headache, Mental status changes, Mood swings, Muscle twitching, Musculoskeletal stiffness, Nausea, Postictal state, Respiratory distress, Somnolence, Tremor, Unresponsive to stimuli

Symptom Text: Nausea and weakness days before menstrual cycle begins since first dose on 5/14/08. Seizure on 07/07/09. Has never had a seizure before. Is not on any prescribed or over-the-counter medications. Has never had any health problems, surgeries or head trauma. 8/4/09 Medical records received DOS 7/8/09 to 7/15/09 Assessment: Grand Mal Seizure. Seen at community hospital previous night post described seizure. Parent reports child made 'gurggle noises' then folded arms and was jerking. Stiff and not responsive. Patient presents with residual headache. Neuro consult 7/15/09 in f/u to seizure event. Pt had reported some shakiness to legs prior to event, possible partial seizures. No memory of event. DX: Grand Mal seizure. 8/12/09 ER Records recieved DOS 7/7/09. Assessment: Seizure disorder, first onset seizure. After visit to dentist patient was observed to have a sudden onset of seizure-like activity. Making an abnormal noise and 'twitching movements'', unresponsive. Transient respiratory distress. Postictal stage in which patient was confused. No incontinence. No recent injury or head trauma. Feels sleepy. Altered mentation. Chest pain. 8/4/09 Medical records received DOS 7/8/09 to 7/15/09 Assessment: Grand Mal Seizure. Seen at community hospital previous night post described seizure. Parent reports child made 'gurggle noises' then folded arms and was jerking. Stiff and not responsive. Patient presents with residual headache. Neuro consult 7/15/09 in f/u to seizure event. Pt had reported some shakiness to legs prior to event, possible partial seizures. No memory of event. DX: Grand Mal seizure. LABS and DIAGNOSTICS: EEG Pending. CT Head and unspecified labs performed at community hospital. PMH: none noted./pc 8/12/09 ER Records recieved DOS 7/7/09. Assessment: Seizure disorder, first onset seizure. After visit to dentist patient was observed to have a sudden onset of seizure-like activity. Making an abnormal noise and 'twitching movements'', unresponsive. Transient respiratory distress. Posti

Other Meds: None

Lab Data: Head CT, chest xray, urine and blood. Negative. 8/4/09 Medical records received DOS 7/8/09 to 7/15/09 LABS and DIAGNOSTICS: EEG Pending. CT Head and unspecified labs performed at community hospital. 8/12/09 ER Records recieved DOS 7/7/09.

History: None.

Prex Illness: No

Prex Vax Illns: Seizure~HPV (Gardasil)~2~13~Patient

Vaers Id: 350953-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	26-Apr-2009		08-Jul-2009	22-Jul-2009	--		29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Impaired driving ability, Injection site erythema, Injection site pain

Symptom Text: My daughter was encouraged to have the Vaccination GARDASIL at our local doctors surgery. She had the first injection, with no side effects, after the second injection, she suffered a terrible seizure. She has been investigated for epilepsy, with a neurologist, but no results could confirm this, we are left confused and unsure of her future. I am convinced that the GARDASIL caused her seizure. We were given no information regarding possible side effects, only that she may have a sore or red arm from the injection, she had a previous history of ITP, which is on her doctors records, but we were asked no previous medical history prior to the nurse giving the injection. I am absolutely disgusted that we were given no information. There is no history of epilepsy in our families, and my daughter was a healthy, fit 19 year old. She has has now lost her driving licence, the possibility of promotion at work, due to no licence, and we have been through hell and back with the worry of all this. How can this happen, someone needs to be accountable for this, this is just not fair. She is not in a relationship, she is not sexually active, so why is this drug being pushed towards young girls, with no thought for necessity, and no time investigating if it is really required for each individual. We have no idea what the long term effects are, I am worried sick that she may have another seizure, and who will be there for her if and when that happens, we are still going through hell with the worry, and I will do whatever it takes to get to the bottom of this.

Other Meds:

Lab Data: Pt was taken to the Hospital the day of the seizure, 26th April 2009, and she was given an ECG and a CT Scan. We have since had 3 EEG's with the Neurologist, and nothing can be found for the cause of the seizure.

History: Pt lived most of her life in the foreign country, just returned to country on a permanent basis with myself, and her father. She suffered with ITP between the ages of 9yrs to 12yrs old, but has had no symptoms in the last 7 years. She is a social smoker, 10 - 15 cigarettes a day, and a social drinker, 1 - 2 days a week, average 4-6 drinks. She has had no other medical conditions.

Prex Illness:

Prex Vax Illns:

Vaers Id: **350967-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		08-Jul-2009	09-Jul-2009	--	WAES0907USA00328	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: It was reported from an article published on 29-JUN-2009 that there were 27 deaths in 2008 said to be associated with GARDASIL. This is one of several reports received from the same source. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **350968-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		08-Jul-2009	09-Jul-2009	--	WAES0907USA00329	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: It was reported from an article published on 29-JUN-2009 that there were 18 deaths said to be associated with GARDASIL. This is one of several reports received from the same source. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 350971-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	28-Feb-2009	01-Mar-2009	1	08-Jul-2009	09-Jul-2009	FR	WAES0907USA00226	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Diplegia, Disturbance in attention, Headache, Syncope, Tremor

Symptom Text: Information has been received from a physician via agency as part of a business agreement (manufacturer control # 20090701JZ3) concerning an approximately 24 year old female who on 28-FEB-2009 was vaccinated with the third dose of GARDASIL (lot# not reported). It was reported that post second dose of GARDASIL (lot# and date not reported), the patient experienced extreme headaches at the base of the neck, for which she saw a chiropractor. On 05-MAR-2009 the patient collapsed at work and was taken by ambulance to the hospital. The following morning (on 06-MAR-2009), a magnetic resonance imaging (MRI) and computed axial tomography (CAT) scan were performed which showed normal results. The patient's blood tests revealed a low white cell count. The patient had paralysis of her left leg and felt weak and was unable to concentrate. The patient described it as she felt as though she was "trembling from the immediate". Prior to returning to work, on 09-MAR-2009, 10-MAR-2009 and 11-MAR-2009 the patient received acupuncture, which was said to have improved her paralysis. Upon returning to work, the patient collapsed again at work on 18-MAR-2009 and was taken to another hospital. Another MRI was performed, which was also normal. The patient returned to work again on 30-MAR-2009, and found she was weak and unable to concentrate. During this time, the patient also visited a homeopath, who prescribed an "antidote" to GARDASIL without effect. Subsequently, the patient recovered. The outcome of the extreme headache at the base of the neck was unknown. Upon internal review, paralysis of left leg was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 06Mar09, normal result; computed axial tomography, 06Mar09, normal result; diagnostic laboratory test, 06Mar09, blood tests revealed a low white cell count; magnetic resonance imaging, 18?Mar09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350972-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Jul-2009	09-Jul-2009	GA	WAES0907USA00233	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first and second dose of GARDASIL on unspecified dates. The patient experienced tonic chronic type seizure activity after getting the second dose of GARDASIL. The patient didn't experience any adverse effect from first dose. Unspecified medical attention was sought. At the time of the report, the patient had recovered. Upon internal review, the tonic chronic type seizure activity was considered as other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **350984-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	08-Jul-2009	08-Jul-2009	0	08-Jul-2009	17-Jul-2009	WA		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Incontinence, Loss of consciousness

Symptom Text: after receiving inj. pt sat down and passed out in waiting room. Out for approx 45sec, pt taken to treatment room here in clinic and seen by attending dr; was given iv fluids and recovered. Pt did loose bladder control. Pt stated she has passed out from imms before.

Other Meds:

Lab Data:

History:

Prex Illness: just released from hosp for unknown reason

Prex Vax Illns:

Vaers Id: **351014-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		09-Jul-2009	10-Jul-2009	FR	WAES0907USA00220	10-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Eating disorder, Headache, Meningitis, Musculoskeletal stiffness, Paraesthesia, Paralysis, Photophobia, Pyrexia, Speech disorder, Viral infection, Vomiting

Symptom Text: Information has been received from a physician via agency as part of a business agreement (manufacturer control # 20090701JZ2) concerning an approximately 20 year old female who was vaccinated with three doses of GARDASIL vaccine at 0, 2 and 6 months respectively. It was reported that the patient was taking an antidepressant medication for 3 months prior to her first dose of GARDASIL. 3 weeks post third GARDASIL, the patient experienced vomiting, fever, headache and pins and needles in her hands and feet. On the same day, the patient visited her doctor who diagnosed it as a viral infection. An hour after returning home from the medical clinic, the patient's headache intensified, and the patient experienced neck stiffness and sensitivity to light. The patient was sent to the hospital by ambulance and suspected to have been suffering from meningitis, and was in a critical condition. Presently (by the time of report on 01-JUL-2009), the patient had been paralyzed in hospital for the past 9 months, and was unable to eat, talk or move. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 351015-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Aug-2007	01-Sep-2007	24	09-Jul-2009	10-Jul-2009	PA	WAES0907USA00275	29-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Activities of daily living impaired, Disturbance in attention, Dizziness, Insomnia, Loss of consciousness, Nausea

Symptom Text: Information has been received from a consumer concerning her 12 year old student daughter with no known drug allergies who on 09-MAY-2007 was vaccinated with the first dose of GARDASIL. On 08-AUG-2007 the patient was vaccinated with the second dose of GARDASIL. In September 2007, the patient developed severe nausea and severe dizziness, unable to function-can't walk, stand up, read, no computer work. The patient could not go to sleep at night because when she closed her eyes the dizziness was even worse, black outs. Symptoms lasted from 10 minutes to several hours. The patient missed a total of 30 days of school in 2007. This year she missed 27 days of school. Symptoms continued. Studies of X-rays, MRI, CT scan, vestibular testing, sleep studies, EEG were all negative. Severe nausea, severe dizziness, black outs, can't walk and missed a total of 30 days of school in 2007 and 27 days this year were considered to be disabling and other important medical events by the reporter. Additional information has been requested. 9/28/09 Note in vaccine records. Patient had 2 doses of Gardasil. Did not complete series.

Other Meds: Unknown

Lab Data: X-ray, negative; magnetic resonance, negative; computed axial, negative; sleep study, negative; electroencephalography, negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 351019-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-May-2009	21-May-2009	7	09-Jul-2009	10-Jul-2009	FR	WAES0907USA00658	10-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Myalgia, Pain in extremity, Similar reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a Health Authority (HA reference number PEI200914058) concerning a 14 year old female with a history of sinus bradycardia and slightly underweight who on 14-MAY-2009 was vaccinated with her second dose of GARDASIL (lot number, injection site and route not reported). Concomitant therapy included contraceptives (not otherwise specified). One week prior to reporting, on 21-MAY-2009 (reporting date form dated 28-MAY-2009), the patient experienced myalgia, pain in limbs and headache. On 27-MAY-2009, the patient experienced syncope. On an unspecified date, she was admitted to hospital. The patient recovered completely on an unknown date. It was reported that after the first vaccination with GARDASIL on 12-JAN-2009, the patient experienced syncope (WAES 0907USA00656). This is one of two reports regarding the same patient. Other business partner numbers included: E2009-05563. Additional information has been requested.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History: Sinus bradycardia; Underweight

Prex Illness:

Prex Vax Illns:

Vaers Id: **351049-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	19-Jun-2009	19-Jun-2009	0	09-Jul-2009	17-Jul-2009	FL		17-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	3	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Myalgia

Symptom Text: It has been over 2 weeks since my last guardasil shot and my left arm is still sore at the injection site. Feels like a sore muscle.

Other Meds:

Lab Data:

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **351057-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Jul-2009	07-Jul-2009	0	09-Jul-2009	17-Jul-2009	MD		20-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0339Y	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2923AA	0	Right leg	Intramuscular	
	HPV4	MERCK & CO. INC.	1497X	0	Left leg	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041BA	4	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site nodule, Injection site swelling, Injection site warmth

Symptom Text: Swelling, redness and warmth at injection site. Approximately 2-3 inches in diameter. Hard knot at sight. Used ice to injection site. S/S X 2 days.

Other Meds:

Lab Data:

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **351059-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	14-Apr-2009	18-Apr-2009	4	09-Jul-2009	20-Jul-2009	NC		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0089U	0	Left arm	Intramuscular	FLU TDAP

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Pt received HPV vaccine on 14 Apr 09. Pt went to urgent care clinic on 24 Apr 09 complaining that her right hand had been numb for the past 6 days. Pt received Gardasil in left arm. When pt came in for 2nd series pt states her hand is still numb and believes it may be related to the Gardasil vaccine.

Other Meds: non per patient

Lab Data: C-spine x-ray that was resulted as normal

History: none per patient

Prex Illness: none per patient

Prex Vax Illns: none~ ()~NULL~~In Patient|none~ ()~NULL~~In Sibling1|none~ ()~NULL~~In Sibling2

Vaers Id: **351066-1 (S)** **Related reports:** 351066-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Dec-2008	07-Dec-2008	5	09-Jul-2009	10-Jul-2009	OR		23-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Right arm	Unknown	FLU

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Blood test, Complicated migraine, Computerised tomogram, Dizziness, Electrocardiogram, Electroencephalogram, Endoscopy, Fatigue, Gastrooesophageal reflux disease, Hyperhidrosis, Hypersomnia, Neurological examination normal, Nuclear magnetic resonance imaging, Ophthalmological examination, Ophthalmological examination normal, Pain, Syncope, Ultrasound scan, Vision blurred, Visual impairment, Vomiting, Weight decreased, X-ray with contrast upper gastrointestinal tract

Symptom Text: Extreme fatigue (sleeping 20-22 hours per day). In Jan. she started to throw up, on 1/19 she had a migraine symptom that was painful and affected her vision for 3 days, vomiting continued for 5 weeks, then fainting started and lasted for a week, extreme fatigue and underlying headache during all this time. In end of April, headache stopped, but fatigue continued. In Jan. patient had a CT scan, EKG and blood work, along with an ophthalmologist appt. In Feb. she got the 2nd dose of Gardasil (we didn't know what was wrong with her). She had an upper GI in Feb. In March she had an endoscope, ultra sound of all her organs, MRI, EEG and more blood work. We are currently seeing a naturpath Dr. trying to "detox" her. 9/22/09 School medical records received DOS 12/14/08 to 2/17/09. Several visits. Patient tired, could not function, slept all day and night, thowing up several times a day. Dizzy, sweaty, feels she will pass out. Vision blurry, poor depth perception. Migraine headache. 9/22/09 PCP medical records received DOS 12/02/08 to 6/19/09. Assessment: Complex Migraines. Patient presents with unexplained vision abnormality. Eye exam normal. Dizzy spells, headaches, vomiting, GERD, weight loss, syncope. Neurology consult - Complex Migraines - otherwise WNL.

Other Meds: YAZ (drospirenone & ethinyl estradiol)

Lab Data: 9/22/09 PCP medical records received DOS 12/02/08 to 6/19/09. LABS and DIAGNOSTICS: CHEM - Glucose 101 mg/dL (H). Biopsy - Duodenum, stomach, gastric body, esophagus - all WNL. CT Head - WNL. MRI- Negative. EEG - Normal. Multiple Positive A

History: 9/22/09 PCP medical records received DOS 12/02/08 to 6/19/09. Menorrhagia. YAZ contraception.

Prex Illness:

Prex Vax Illns: ~HPV (Gardasil)~~0~Patient

Vaers Id: **351066-2 (S)** **Related reports:** 351066-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Dec-2008	01-Dec-2008	0	13-Jul-2009	14-Jul-2009	OR	WAES0907USA00771	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Fatigue, Hypersomnia, Immediate post-injection reaction, No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with no pertinent medical history and no drug reactions or allergies who in approximately October 2008, was vaccinated with a first dose of GARDASIL vaccine (lot # not reported) intramuscularly. In December 2008 she received second dose of GARDASIL (lot # not reported) intramuscularly. In the same visit in December 2008, she received a dose of VAQTA (manufacturer unknown). There was no concomitant medication. In December 2008" right after the dose" of GARDASIL vaccine the patient developed chronic fatigue, fainting spells. The patient slept 20 hours a day and had not been attending school. The patient sought medical attention was at office. At the time on the report on 06-JUL-2009 the patient had not recovered. On unspecified date psychiatrist evaluation was performed (results not reported). The patient did not experience any adverse effects after the first dose of GARDASIL. The physician mentioned that he did not feel that the symptoms were related to GARDASIL. Chronic fatigue, fainting spells, slept 20 hours were considered to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **351067-1 (S)** **Related reports:** 351067-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Jun-2007	14-Jun-2007	0	09-Jul-2009	10-Jul-2009	NJ		02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1503F		Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2688AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1210U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Aphonia, Asthenia, Chest discomfort, Cough, Crying, Dizziness, Dysgeusia, Dyspnoea, Fatigue, Headache, Hypersensitivity, Injection site pain, Injection site swelling, Laryngitis, Malaise, Respiratory tract congestion, Restless legs syndrome

Symptom Text: Coughing, trouble breathing, loss of voice, malaise, crying, headache, chest discomfort, pain at injection site with swelling, dizziness, abdominal pain, weakness, fatigue, restless legs. 7/10/09 Received ER medical records of 5/10/2007. FINAL DX: laryngitis Records reveal patient had chest congestion, dry cough, abnormal taste x 1 week. Seen by PCP & dx w/allergies. OTC allergy med not helpful. Tx w/oral antibiotics & cough syrup. D/C to home w/PCP f/u. 11/23/09 Merdical recs received for date 5/7/07. OV for c/o sore throat. DX: postnasal drip. OV 5/14/07 c/o sore throat f/u ER visit. DX: postnasal drip.

Other Meds:

Lab Data: LABS: CXR WNL.

History: none

Prex Illness: None

Prex Vax Illns:

Vaers Id: **351067-2 (S)** **Related reports:** 351067-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Jun-2007	14-Jun-2007	0	09-Sep-2009	10-Sep-2009	--	WAES0908USA03598	10-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1210U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Aphonia, Asthenia, Chest discomfort, Cough, Crying, Dizziness, Dysgeusia, Dyspnoea, Fatigue, Headache, Hypersensitivity, Injection site pain, Injection site swelling, Laryngitis, Malaise, Respiratory tract congestion, Restless legs syndrome

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 13 year old female who on 14-JUN-2007, was vaccinated with the third dose of GARDASIL IM into her left arm (lot # 655154/1210U). On 14-JUN-2007 the patient experienced abdominal pain, aphonia, asthenia, chest discomfort, cough, crying, dizziness, dysgeusia, dyspnoea, fatigue, headache, hypersensitivity, injection site pain, injection site swelling, laryngitis, malaise, respiratory tract congestion and restless legs syndrome. The symptoms included coughing, trouble breathing, loss of voice, malaise, crying, headache, chest discomfort, pain at injection site with swelling, dizziness, abdominal pain, weakness, fatigue, restless legs. There was no pre-existing illness. The patient required an emergency room visit (ER) visit. On 10-JUL-2009 ER medical records of 10-MAY-2007 was received. The final diagnosis was laryngitis. Records revealed patient had had chest congestion, dry cough and abnormal taste for 1 week. The patient was seen by a primary care physician (PCP) and diagnosed with allergies. Over the counter (OTC) allergy medication was not helpful. A chest X-ray (CXR) was within normal limits. The patient was treated with oral antibiotics and cough syrup. The patient was discharged to home with PCP follow up. The listing indicated that one or more of the events was considered to be disabling and immediately life-threatening. No further information is available. The original reporting source was not provided. The VAERS ID# is 351067. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released.

Other Meds: Unknown

Lab Data: chest x-ray, within normal limits

History: Laryngitis; Respiratory tract congestion; Dry cough; Taste abnormality

Prex Illness:

Prex Vax Illns:

Vaers Id: **351077-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	30-Jun-2009	02-Jul-2009	2	09-Jul-2009	20-Jul-2009	PA		20-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	5	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Injection site erythema, Injection site pain, Injection site rash

Symptom Text: Patient received GARDASIL and DTaP in left arm. Patient had allergic reaction to GARDASIL, come in on 7-29-09 to report. small red rash and soreness at injection site.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 351099-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		10-Jul-2009	13-Jul-2009	FR	WAES0906USA03817	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Areflexia, Biliary colic, Dizziness, Faeces discoloured, Guillain-Barre syndrome, Hypokinesia, Malaise, Mental status changes, Pain in extremity, Sensory loss, Vomiting

Symptom Text: Initial information was reported on 15-JUN-2009 by the mother of the patient. Additional information was received on 16-JUN-2009 from a health care professional concerning a 17 year old female who in April 2008 was vaccinated with the first dose of GARDASIL (batch number unknown) and the second dose of GARDASIL (batch number unknown) on 30-JUN-2009. In August 2008 the patient was hospitalized and diagnosed with GUILLAIN-BARRE syndrome. The outcome was not reported. Case is closed. Follow-up information has been received from patient's physician on 30-JUN-2009. According to the medical records the patient was hospitalized from 17-AUG-2008 to 26-AUG-2008 after being diagnosed with GUILLAIN-BARRE syndrome. During the period from September to December 2008 the patient was hospitalized for one month and then received non-institutional care (physical therapy) three times per week. On 08-JAN-2009 the patient reported malaise, pain in arms and legs, abdominal pain and bright colored feces to the doctor (onset on unspecified date). The patient was treated with CITODON (BIOPHAUSIA), DEXOFEN (BIOPHAUSIA), and SPASMOFEN (MEDA) to relieve the pain. The doctor was hesitant due to GUILLAIN-BARRE syndrome to prescribed Selective serotonin reuptake inhibitors (SSRIs) for her ability to make decisions. On 10-FEB-2009 she visited the doctor. The doctor described the patient's situation after the physical therapy (during September to December 2008) as a very tough period with total loss of sensibility and peripheral loss of the ability to move. The symptoms has gradually gone into regress and she had now regained a lot of her former energy and ability even though she still had some way to go before she would be completely recovered. The patient still experienced heavy loss of reflexes. The most complicated thing had been the attacks of pain in the abdomen that on five occasions had caused her to seek medical attention at the ER (dates not reported). The pain appeared and worsened within 5-10 minutes and could then last for several h

Other Meds: Unknown

Lab Data: Blood pressure measurement, 10Feb09, 95/60; WBC count, slightly increased

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 351100-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-May-2009	22-May-2009	0	10-Jul-2009	13-Jul-2009	FR	WAES0907USA00142	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Chest discomfort, Convulsion, Dizziness, Dyspnoea, Feeling of body temperature change, Flushing, Headache, Heart rate increased, Hot flush, Hypoventilation, Insomnia, Loss of consciousness, Oropharyngeal pain, Palpitations, Panic attack, Polydipsia, Syncope, Tremor, Viral infection, Vomiting

Symptom Text: Information has been received from a consumer via CSL as part of a Business agreement (manufacturer control # 20090701JZ1) concerning an 18 year old female patient who on 22-APR-2009 received the first dose of GARDASIL and on 22-MAY-2009 the second dose of GARDASIL. Ten to 15 minutes after the second dose, the patient felt faint. In the following couple of days, the patient experienced fainting, vomiting, severe headaches and stomach aches. The patient was reported to have been drinking water excessively in the nights following the second dose of GARDASIL. On 14-JUN-2009, the patient developed sore throat and saw the physician on 16-JUN-2009 who diagnosed her as having a virus. On 17-JUN-2009, the patient had a sleepless night, awaking at 3 am to go to the bathroom, when she experienced extreme pressure on the left side of her head. Upon returning to bed, the patient had hot and cold flushes, extreme palpitations and pressure on her head and chest. The patient then experienced an extreme panic attack and was taken to the hospital where her heart rate measured 150. On 18-JUN-2009, the patient felt very dizzy, headache, and pressure on her chest. On 19-JUN-2009, the patient experienced seizures, shaking violently from shoulder down to hands, the shaking alternating from left to right side, and blacked out for one to two minutes at a time. The patient was taken to the hospital for investigation. The neurologist prescribed APILIM, which the patient took from 19-JUN-2009 to 21-JUN-2009. The patient's MRI was normal but her EEG showed at irregular brain pattern. Presently, the patient was still experiencing difficulty sleeping with rapid, shallow breathing when asleep and problems with breathing.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, ??Jun09, normal; electroencephalography, ??Jun09, irregular brain pattern; total heartbeat count, 17Jun09, 150

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **351101-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		10-Jul-2009	13-Jul-2009	AR	WAES0907USA00248	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse concerning a "12 year old" female who was vaccinated with her 1st dose of GARDASIL, 0.5ml, IM. The patient also received another 4 different vaccines (unspecified) and a few hours later the mother called and reported her daughter had a seizure. The patient had sought medical attention. The outcome was unknown. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 351129-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Jul-2009	10-Jul-2009	3	11-Jul-2009	21-Jul-2009	NY		06-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Seizure 7:30PM on 7/10/09 and at 8:30am while asleep. 8/5/09 Primary care provider medical records received DOS 6/17/09 to 7/14/09. Includes portion of neurological consultation records previously abstracted and coded. Assessment: Seizures. Parent has informed primary care provider that child has had 3 seizures since vaccine administration.

Other Meds:

Lab Data: 8/5/09 Medical records received DOS 6/17/09 to 7/14/09. LABS and DIAGNOSTICS: Iron 12 ug/dL (L) UIBC 388 ug/dL (H) (Transferrin)Saturation 3% (L) SGPT/ALT 27 U/L (L) ALK PHOS 151 U/L (H)

History: seizure disorder complex partial seizures. 7/31/09 Neurological consultation records received DOS 4/1/02 to 4/07/09. All consultant records are dated prior to the adverse event onset. Unprovoked generalized seizure disorder at age 3. Febrile seizures. Partial seizures with generalization. Tonic-Clonic Seizures. Jaw/face/teeth injured - multiple surgeries. Side to side, in and out j

Prex Illness: Prior seizure disorder

Prex Vax Illns:

Vaers Id: **351133-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Oct-2007	01-Jan-2008	92	12-Jul-2009	22-Jul-2009	TX		22-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	N/A	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstrual disorder

Symptom Text: after the third vaccine of GARDISIL i stoped getting my period, now if i dont take birth controls i wont get my period.

Other Meds: Birth control, advil

Lab Data: Went to dr, and got my anual check up everything was normal, but if i stop taking my birth control i dont get my period.

History: club foot, sinus, food allergies

Prex Illness: n/a

Prex Vax Illns:

Vaers Id: **351148-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	11-Jun-2009	11-Jun-2009	0	10-Jul-2009	21-Jul-2009	NY		21-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea

Symptom Text: 4 hours after receiving vaccine pt c/o H/A dizziness and nausea that lasted 5 hours.

Other Meds:

Lab Data:

History: Penicillin

Prex Illness:

Prex Vax Illns:

Vaers Id: 351150-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Jun-2008	27-Jun-2008	1	10-Jul-2009	21-Jul-2009	NY		21-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0870X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Epstein-Barr virus antibody positive, Erythema nodosum, Eye swelling, Headache, Infectious mononucleosis, Lymphadenopathy, Malaise, Mononucleosis heterophile test positive, Myalgia, Pyrexia

Symptom Text: 1 day after GARDASIL developed fever, myalgias, swollen eyes; diagnosed with "mono". Monospot (+) however EBV titers all negative. Never felt completely well -> recurrent myalgias, swollen glands, headache. EBV IgG titers (+) 11/08. Multiple complaints myalgias, knee pain; erythema nodosum diagnosed 4/09.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 351154-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Jul-2009	09-Jul-2009	0	10-Jul-2009	22-Jul-2009	WA		22-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lacrimation increased, Loss of consciousness, Pallor

Symptom Text: Pt A and O x3. HPV given L deltoid. Pt passed out 1-2 secs after vaccine given. Pt arousable. A and O x 3. Vital signs stable. Pt tearful and pale. Pt states she had not eaten or drank anything. Pt given 8 oz apple juice.

Other Meds:

Lab Data:

History: Spina Bifida Occulta; acne; Headache; asthma; allergies

Prex Illness:

Prex Vax Illns:

Vaers Id: 351171-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		13-Jul-2009	14-Jul-2009	FR	WAES0907AUS00002	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Autoimmune disorder, Central nervous system inflammation, Dyspnoea, Gait disturbance, Pleurisy, Wheezing

Symptom Text: Information has been received from media monitors and via agency as part of a business agreement concerning a 26 year old fit and healthy female who was vaccinated with GARDASIL. Subsequently two weeks after receiving GARDASIL, the patient found it difficult to breathe. The patient reported that she was limping around the house like a stroke victim, wheezing and worried she was suffocating. The patient went straight to a hospital emergency room. At the hospital, the patient had x-rays, blood tests and an MRI. The patient was told that the lining of her left lung become so inflamed that it was rubbing against her chest wall each time she breathed. A medical consultant told her that she must have picked up some mysterious virus. She was released with no diagnosis other than pleurisy and was given painkillers (not specified). Five months after receiving the vaccine a neurologist confirmed that she had damage to her left side and it was an autoimmune reaction, resulting in inflamed lining of the left lung and nerves on the left side with a temporal connection to GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: X-ray, left lung inflamed; diagnostic laboratory test; magnetic resonance imaging, left lung inflamed

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **351172-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		13-Jul-2009	14-Jul-2009	--	WAES0907USA00189	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Adverse event

Symptom Text: Information has been received from a registered nurse concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). The registered nurse reported "somebody that works within the community health center's child received the dose of GARDASIL, at another office (which was not specified) and experienced a serious adverse event where she could not walk among other things which were unspecified". The registered nurse reported that the patient was hospitalized and the length of stay was unspecified. All telephone attempts to obtain follow up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 351173-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Aug-2007	01-Aug-2007	0	13-Jul-2009	14-Jul-2009	MD	WAES0907USA00372	17-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Balance disorder, Cerebral atrophy, Chronic sinusitis, Convulsion, Headache, Infectious mononucleosis, Migraine, Muscle spasms, Otitis media, Paraesthesia, Petit mal epilepsy, Rash, Speech disorder, Staring, Syncope, Upper respiratory tract infection, Urinary tract infection

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter with no pertinent medical history and no known drug allergies/drug reactions who "in August 2007" was vaccinated with the first dose of GARDASIL on the right arm. The patient received the second dose in December 2007. There was no concomitant medication reported. It was reported that "within the week of the first vaccination" the patient had been experiencing seizures and fainting after having first dose of GARDASIL. It was reported that the patient started to feel "electric shocks" on the right side of the body along with muscles spasms. She also had strange headaches and petit mal seizures. The patient saw a physician. An electroencephalogram (EEG) and magnetic resonance imaging (MRI) were performed (results not provided). It was reported that the patient had not recovered at the time of the report. Upon internal review, the events of seizures and petite mal seizures were determined to be other important medical events. Additional information has been requested. 9/15/09 Received PCP medical records. FINAL DX: atypical HA; possible seizures Records reveal patient experienced rash, mono, OM, migraine HA, URI, UTI, abdominal pain, fibula fracture from diving accident, . Referred to dermatology & neuro. Neuro eval of 10/08 revealed atypical HA, electric shock type pain, staring spells, mild speech difficulty, intermittent balance problams. Tx w/meds & improved.

Other Meds: None

Lab Data: Unknown 9/15/09 Received medical records w/LABS: monospot (+). CT brain WNL except for mild diffuse brain atrophy. MRI/MRA brain WNL except for chronic sinusitis. EEG abnormal.

History: None 9/15/09 Received medical records w/PMH: viral meningitis age 6 yr. Family Hx: MS, migraines.

Prex Illness:

Prex Vax Illns:

Vaers Id: **351174-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jun-2009	03-Jun-2009	0	13-Jul-2009	14-Jul-2009	FR	WAES0907USA00661	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain

Symptom Text: Information has been received on 03-JUL-2009 from a pediatrician through the health authorities concerning a 16 year old female who on 03-JUN-2009 was vaccinated intramuscularly with the second dose of GARDASIL (lot# not reported). On 03-JUN-2009 the patient developed a very severe pain at the injection site during 3 days, to the point that she could not raise her arm anymore, and the pain decreased but was still ongoing on 26-JUN-2009. Ice and NSAID's were suggested to the patient, but she did not apply the treatment. At the time of reporting the patient had not yet recovered. As per the reporter this was a medically significant event due to a temporary incapacity. Other business partner numbers included: E2009-05627. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351176-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Oct-2008	Unknown		13-Jul-2009	14-Jul-2009	FR	WAES0907USA00783	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1147U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mononeuritis, Pain in extremity, Vaccine positive rechallenge

Symptom Text: Information has been received on 02-Jul-2009 from a gynaecologist concerning an 18 year old female who on 28-OCT-2008 was vaccinated with the first dose of GARDASIL (lot#1147U, batch# NH17630, route and site of administration not reported). On 27-JAN-2009 the patient was vaccinated intramuscularly the second dose of GARDASIL (lot# not reported) into the upper arm. After the first vaccination with GARDASIL the patient experienced pain in arm. Duration not reported. After the second vaccination the patient experienced pain in her arm. Pain was more intense than after the first vaccination. Patient was referred to a neurologist who diagnosed a mononeuritis by irritation of a nerve. The patient was treated with gabapentin, and she refused the third dose of GARDASIL. The outcome was not reported. Mononeuritis was considered to be other medically important condition by the reporter. Other business partner numbers included: E200905634. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 351177-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Jun-2009	04-Jun-2009	0	13-Jul-2009	14-Jul-2009	FR	WAES0907USA01044	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0772X	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Gait disturbance, Hyperhidrosis, Hypotension, Pallor, Pyrexia

Symptom Text: Information has been received from a health authority (case n. 100814) through foreign agency (local case n. IT280/09). A 12 year old female with no previous medical history reported was vaccinated on 04-JUN-2009, with the third dose of GARDASIL (Lot number 0772X and Batch number NK15900). On the same day, about 8 minutes post vaccination, she presented with an abrupt decline in blood pressure, faintness (total loss of deambulating ability and marked pallor) without loss of consciousness: profuse sweating that lasted up until admission to the hospital (4 hours later). She was hydrated and given sugar orally in the vaccination clinic and rehydrated by i.v. and treated with paracetamol (onset of slight fever the first night of admission, not reported as an adverse event) during admission. The outcome was recovered on 06-JUN-2009. The case is closed. Relevant Test/Laboratory data: Low diastolic blood pressure: 45. EEG: within normal range. EEG: normal. Increased leukocytes: 13250. RBC. 5. 230000/mmc; hemoglobin 14.9 g/dl, hematocrit 42.2%; platelets 250.000/mmc; C-reactive protein 0.3 mg/L; glycemia 102 mg/dL; sodium 137 mEg/L; potassium 4 mEg/L; calcium 9.6 mg/dL; Creatininemia 0.79 mg/dL; SGOT 19 u/L; SGPT 8 U/L; blood analysis gas within normal range; urine analysis within normal range. Neurological evaluation : within normal range. Other business partner numbers included: E2009-05666. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure measurement, 45, low diastolic blood pressure; electroencephalography, within normal range; electrocardiogram, normal; neurological examination, within normal range; WBC count, 13250; hematocrit 42.2, %; hemoglobin, 14.9, g/d

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 351194-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	02-Jul-2009	02-Jul-2009	0	13-Jul-2009	22-Jul-2009	NY		22-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised, Rash pruritic

Symptom Text: PATIENT COMPLAINED OF AN ITCHY RASH ALL OVER HER BODY. THE RASH BEGAN SEVERAL HOURS AFTER THE VACCINE WAS ADMINISTERED.

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351214-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jun-2009	26-Jun-2009	0	13-Jul-2009	22-Jul-2009	CA		22-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	9725103	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fear, Nausea, Syncope

Symptom Text: Scared before injection. Syncopal episode after injection recovered after lying down. Mom reports nausea for few hours after.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351225-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Jun-2009	05-Jun-2009	0	13-Jul-2009	22-Jul-2009	GA	GA09023	22-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3029AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334EA	0	Right arm	Unknown	
	HIBV	GLAXOSMITHKLINE BIOLOGICALS	AVBVB610AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0315Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2906AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Loss of consciousness, Malaise

Symptom Text: Received 5 immunizations. After receiving last immunization c/o not feeling well, passed out + hit head on floor.

Other Meds: No

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **351300-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	02-Jul-2009		14-Jul-2009	24-Jul-2009	--		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anorexia, Cough, Nausea, Oropharyngeal pain, Pyrexia, Streptococcal identification test negative

Symptom Text: Daughter has adverse reaction to Gardasil, she has had continuous fever 104 07/10/09 nausea Dr thought might be strep, however strep test negative. Continues to have high fever, no appetite, sore throat, cough.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 351302-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	16-Oct-2008	16-Oct-2008	0	14-Jul-2009	15-Jul-2009	FR	WAES0906USA04893	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0353U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Cyanosis, Syncope, Unresponsive to stimuli

Symptom Text: Information was obtained on request by the company from the agency via a public case detail concerning a 23 year old female patient who on 16-OCT-2008 was vaccinated with a dose of GARDASIL (Lot # 0353U and Batch # NG51820) intramuscularly. It was reported that on 16-OCT-2008 the patient experienced syncope and convulsion. Child felt well after having had GARDASIL, but within about a minute after receiving GARDASIL, the patient collapsed onto the floor and looked to be fitting and unresponsive. The patient regained consciousness within 20 seconds and the colour remained grey. The patient required a visit to the doctor. The charted blood pressure was 117/70 (lying with feet elevated). Pulse was 57 and regular. The blood sugar level was 9.6 (post prandial, 1 hour) and Glasgow coma scale was reviewed by GP (was observed for 15 minutes further). The patient had recovered at the time of the report. On 02-FEB-2009, the patient had since reviewed dose 2 number AEFI. The vaccine was administered by the GP lying down. The patient reports that her sister had a similar reaction to her first GARDASIL dose. The agency considered that syncope and convulsion were possibly related to vaccination with GARDASIL. The original reporting source was not provided. Follow-up information reported that the agency considered convulsion to be serious as an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: blood pressure measurement, 117/70, lying with feet elevated; blood glucose, 9.6, post prandial, 1 hour; Glasgow coma scale, reviewed by General Practitioner; observed for 15 minutes further; total heartbeat count, 57, regular

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **351304-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Jun-2009	18-Jun-2009	0	14-Jul-2009	15-Jul-2009	CA	WAES0907USA00742	16-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Grand mal convulsion, Immediate post-injection reaction, Loss of consciousness, Pallor, Syncope, Tremor

Symptom Text: Information has been received from a certified medical assistant concerning a 17 year old female patient who on 18-JUN-2009 was vaccinated with 0.65 ml of the first dose of GARDASIL (Lot:661766/0652X). There was no concomitant medication. Immediately after vaccination the patient had a seizure. They called an ambulance, and by the time the ambulance got there the patient was fine and laughing and did not need to leave in the ambulance. Additional information has been received from an office person who stated that the patient's DOB was 13-MAY-1992. After the 17 year old female patient received GARDASIL she began to shake, became unconscious and had a tonic- clonic seizure that lasted for 15 seconds. An Ambulance was called to take the patient to the hospital. The patient "came to and was fine". The patient was not postictal, had no rash and had no difficulty breathing. The patient's blood pressure and EKG were normal. The patient's mother did not want the patient to go to the Emergency Room. The physician evaluated the patient and recommended that the patient have a CT scan of the brain and an EEG. The patient was approved for both diagnostic tests. The patient's mother took the patient home. Upon internal review, tonic-clonic seizure was considered to be an Other Important Medical Event. Additional information has been requested. 7/16/09 PCP recs rec'd. WCC 6/18/09 with normal exam except hematoma under 2 toe nails. HPV#1 given. Pt immediately devloped pallor and syncope with tonic/clonic seizure activity lasting 5-10 sec. EMS called but parent declined transport.

Other Meds: None

Lab Data: electrocardiogram, 06/18/09, normal; blood pressure, 06/18/09, normal. Labs and Diagnostics: CT brain (-). EEG normal.

History: Unknown

Prex Illness: hematoma under 2 toe nails

Prex Vax Illns:

Vaers Id: **351305-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Jul-2009	06-Jul-2009	0	14-Jul-2009	15-Jul-2009	FR	WAES0907USA01018	15-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0160X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Clonus, Epilepsy, Gaze palsy, Hypotonia, Immediate post-injection reaction, Loss of consciousness, Memory impairment, Syncope, Vertigo

Symptom Text: Information has been received from a pediatrician concerning a 17 year old female patient with no relevant medical history reported who received the second dose of GARDASIL (Lot # 0160X and Batch # NJ11070) on 06-JUL-2009. Immediately after vaccination, she experienced a syncope associated with a "mini epileptic fit". She developed initially vertigos, then she lost rapidly consciousness, she presented a revulsion of the eye balls and clonic movements of lower and upper limbs. The revulsion of the eyeballs lasted for a few seconds. The loss of consciousness lasted for 2-3 minutes. The patient was being laid down. The events evolved into hypotonia. Furthermore, the patient had no memory of the episode. The patient's blood pressure and pulse were checked when the episode was over and were normal. To be noted that she had not experienced apprehension nor pain. The patient spontaneously recovered. The reporter considered this case as serious and was reluctant to administer the third dose. According to him, the reaction was linked to the vaccine. The primary reporter considered the patient's adverse experiences to be other important medical events. Other business partner numbers include: E2009-05691. No further information is available.

Other Meds: Unknown

Lab Data: Blood pressure measurement, normal; Total heartbeat count, normal

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	03-Jul-2009	Unknown		14-Jul-2009	23-Jul-2009	TX		29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0043Y	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0558X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: The child had an episode of dizziness after receiving GARDASIL and VARIVAX #2 fainted for <1 minute (20 seconds) but recovered well right away.

Other Meds:

Lab Data:

History: epilepsy

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351323-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Jul-2009	06-Jul-2009	0	14-Jul-2009	23-Jul-2009	--		29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	1312X	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	AHAVB334EA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness

Symptom Text: Pt became light headed. Blood pressure 70/40 but elevated to 90/60 within 15 minutes. No other adverse effects observed. Remained alert and oriented.

Other Meds:

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351325-1** **Related reports:** 351325-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Jul-2009	13-Jul-2009	0	14-Jul-2009	24-Jul-2009	IL		24-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Headache, Malaise, Pyrexia

Symptom Text: 90 minutes after receiving vaccine client experienced headache. She took ibuprofen but didn't receive any relief until second dose taken 4 hours later. Symptoms progressed to fever of 102 degrees F, stomache and general malaise. Took additional ibuprofen this morning at 8:00 am. At 9:30 am temperature is currently 99.8 degreees F. General malaise continues. Has private physician. Advised to consult with him and monitor for progression or worsening of symptoms. Mother is declining further doses of vaccine for daughter.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **351325-2** **Related reports:** 351325-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Jul-2009	13-Jul-2009	0	14-Jul-2009	24-Jul-2009	IL		24-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	UNKNOWN MANUFACTURER	NULL	2	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dizziness, Headache, Hyperacusis, Malaise, Muscle spasms, Myalgia, Pyrexia, Vomiting

Symptom Text: sensitivity to noise within 1/2 hour; severe headace within 1 1/2 hour; uncorrected by ibuprofen; fever within 5 hours 101.9, lowered to 99.8 by two doses of ibuprofen; muscle aches over all body; leg cramps; stomach ache; vomitting x 2; generalized feeling sick all over; lightheaded

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns: arm pain at injection site; not sure if there were any other symptoms~HPV (Gardasil)~1~17~In Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Jul-2009	13-Jul-2009	0	14-Jul-2009	23-Jul-2009	FL		17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1131X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF484CA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2907BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Dizziness, Orthostatic hypotension, Oxygen saturation normal

Symptom Text: About 20 seconds after administering HPV in R delt pt felt "dizzy" pulse 58 and BP 98/52 w/anxiety and orthostatic hypotension. After 30 min pt felt much better B/P 110/72 and was able to walk out unassisted. Pulse OX 98-99%. After lying down.

Other Meds:

Lab Data: Vitals

History: PCN; Cephalosporins

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351359-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Jul-2009	13-Jul-2009	0	14-Jul-2009	24-Jul-2009	CA		24-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3068AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1497X		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	0492Y		Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	U2929AA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Pallor, Unresponsive to stimuli

Symptom Text: 1600 pt passed out, in the lobby on their way out home. Became pale, non responsive, US taken & showed for few minutes as inquiry noted. MD notified. regained consciousness & recovered.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351423-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jul-2009	01-Jul-2009	0	15-Jul-2009	16-Jul-2009	FL	WAES0907USA01326	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Fall, Head injury, Vomiting

Symptom Text: Information has been received from a health professional concerning a 15 years old female who was vaccinated with GARDASIL last week, approximately in July 2009. After vaccination the patient waited 15 minutes before leaving the office. She hit her head when she fell. She also experienced vomiting later that day. The patient was hospitalized that day. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351426-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		15-Jul-2009	16-Jul-2009	CO	WAES0907USA01296	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Coma

Symptom Text: Information has been received from a physician concerning a 23 year old female patient who on an unknown date was vaccinated with a dose of GARDASIL. Within 24 hours of receiving GARDASIL the patient went into a coma. The patient sought unspecified medical attention. The patient's final outcome was not reported. Upon internal review coma was considered to be another important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **351427-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Jun-2009	Unknown		15-Jul-2009	24-Jul-2009	NH		18-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: This child developed hives within 48 hours of her first HPV. She had no other obvious cause for her hives.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 351428-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Jul-2008	01-Mar-2009	229	15-Jul-2009	16-Jul-2009	AZ	WAES0907USA00930	24-Jul-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233BA	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	1967U	0	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	U2569AA	0	Left arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC57B019AB	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Cranial nerve disorder, Dyspnoea, Erythema, Facial palsy, Facial paresis, Fall, Inflammation, Laboratory test, Muscular weakness, Myasthenia gravis, Myasthenia gravis crisis, Overdose, Respiratory failure, Syncope, Thymectomy

Symptom Text: Information has been received from a Physician Assistant concerning a 12 year old female patient with pertinent medical history reported as none and drug reactions or allergies reported as none who on 15-JUL-2008 was vaccinated with a first dose of GARDASIL (lot # 660387/1967U) 0.5ml (also reported mg) intramuscularly. Concomitant therapy included prednisone and PRILOSEC. In March 2009 the patient experienced difficulty breathing. She was taken to the hospital and "as per mom she was given an adult dose of morphine and went into respiratory failure". She later was unable to smile or move her face. Her cranial nerves were affected and she was seen by neurology. Later she was sent to a hospital for myasthenia gravis crisis. She had been hospitalized 3-4 times and she had received rehabilitation therapy. Most recently approximately on 16-JUN-2009, she had a "thymomectomy", secondary to myasthenia. The Physician Assistant and Physician did not feel the events were connected with GARDASIL. At the time of the report on 07-JUL-2009 the patient was recovering. There were many unspecified laboratories and diagnostics tests performed results not reported. She had not received any additional doses of GARDASIL. Difficulty breathing, respiratory failure, cranial nerves affected, given adult dose of morphine, and myasthenia gravis crisis were considered to be immediately life-threatening, disabling and other important medical events. "Given adult dose of morphine" was considered to be an overdose. Additional information has been requested. Medical records received DOS 7/15/08 to 7/7/09. Assessment: Myasthenia Gravis. Patient presents with continued fainting. Can't raise arms, not able to cough, laugh, very weak. Falls, drops things. Redness and inflammation where spinal tap was done. Facial weakness. PMH: \ksk

Other Meds: Morphine; PRILOSEC; prednisone

Lab Data: Unknown. Medical records received DOS 7/15/08 to 7/7/09. LP

History: None. Medical records received DOS 7/15/08 to 7/7/09. Ear pain, sore throat.

Prex Illness:

Prex Vax Illns:

Vaers Id: 351429-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		15-Jul-2009	16-Jul-2009	FR	WAES0907AUS00003	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Diplegia, Pain, Vaccine positive rechallenge

Symptom Text: Information has been received from an on line media article via agency as part of a business agreement concerning a healthy 15 year old female who was vaccinated with the first dose of GARDASIL. Subsequently the patient experienced severe lower back pain and paralysis of the legs and spent six weeks in hospital. The patient was advised to get the second dose of GARDASIL. Within two hours of receiving her second dose of GARDASIL, the patient experienced paralysis of the legs again. It was reported that "they just gave out on her while she was walking along". Twelve month later, the patient almost drowned, her leg paralysis recurs regularly and she was re-admitted to hospital. The patient is in excruciating pain and the daily physiotherapy makes it worse. Morphine helps her sleep for a few hours but then the pain starts again. The patient's relatives say that not one medical person would say that GARDASIL was responsible for her condition and despite an MRI no one has a diagnosis. This is one of several reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 351431-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
42.0	F	Unknown	25-Jun-2008		15-Jul-2009	16-Jul-2009	FR	WAES0907PHL00001	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Inappropriate schedule of drug administration, Neonatal disorder, Urinary tract infection

Symptom Text: Information has been received from a 42 year old female physician with a history of urinary tract infection, 1 pregnancy and 1 live birth through caesarean delivery who in June 2008, was vaccinated with GARDASIL. There were no concomitant medications. Subsequently, she became pregnant. Date of last menstrual period was 25-JUN-2008. The remaining two doses were not given. In June 2008, the patient experienced vaccination exposure during pregnancy. During the course of pregnancy, the mother experienced urinary tract infection which was treated with antibiotics. Urinary tract infection was considered not related to GARDASIL. In April 2009, she gave birth to a live female infant through repeat c-section. The second dose was given to the mother on the 1st week of May 2009. In May 2009, the infant experienced faint murmurs which were detected through 2D echo done on the same month. It was noted that the infant had normal heart sounds during the previous month. Upon Consultation with a pediatrician, the parents were advised to observe the infant for another month as this might resolve spontaneously. In June 2009, 2D echo was again done and showed the same results. The patient's mild pulmonic stenosis persisted. The reporting physician said that both she and her husband had no history of cardiac problems. Relationship of pulmonic stenosis with GARDASIL is unknown at the time of reporting. No further information is available.

Other Meds: Unknown

Lab Data: echocardiography, ??Apr09, normal; echocardiography, ??May09, with murmurs; echocardiography, ??Jun09, mild pulmonic stenosis

History:

Prex Illness: Pregnancy NOS (LMP = 25Jun08)

Prex Vax Illns:

Vaers Id: 351432-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Apr-2009	09-Jun-2009	61	15-Jul-2009	16-Jul-2009	FR	WAES0907HKG00002	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Incontinence, Loss of consciousness

Symptom Text: Information has been received from a registered nurse concerning her daughter, 13 year old female who on 09-APR-2009 was vaccinated with first dose of GARDASIL. The nurse vaccinated her daughter for the second dose of GARDASIL at home on 09-JUN-2009 at around 8:30am. After 5 minutes of vaccination, the patient experienced loss of conscious, convulsion. After CPR, the patient regained conscious but incontinence started to appear subsequently. She was sent to ER at that night. ECG and blood test were performed and the results were normal. Per doctor advice, she was hospitalized for 1 day and CT Plain was also conducted on that night with normal result. After recovering from the above adverse events, she was discharged and MRI was conducted on 03-JUL-2009 and the result was awaiting. EEG was also planned on 11-AUG-2009. Both MRI and EEG were performed by the reporter requested. Causality was unknown as determined by ER doctor. Additional information is not expected.

Other Meds: Unknown

Lab Data: electrocardiogram, 09Jun09, Normal; diagnostic laboratory test, 09Jun09, Normal; computed axial tomography, 09Jun09, Normal; magnetic resonance imaging, 03Jul09, Awaiting for result

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351442-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jul-2009	16-Jul-2009	FR	WAES0907AUS00004	16-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pancreatitis

Symptom Text: Information has been received from an on line media article via CSL as part of a business agreement concerning a female patient who was vaccinated with GARDASIL. Subsequently the patient developed pancreatitis. It was reported that the patient continues to suffer from pancreatitis. Upon internal medical review, pancreatitis was considered an other important medical event. This is one of several reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351469-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	13-Jul-2009	13-Jul-2009	0	15-Jul-2009	24-Jul-2009	CA		27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Asthma, Chest pain, Diarrhoea, Injection site pain, Malaise, Nausea, Wheezing

Symptom Text: Nausea, chest pain, asthsma, diarrhea. 7/17/09 Medical records received DOS 7/13/09 to 7/17/09. PAP test and Gardasil administered. Next day patient c/o pain at injection site, mild chest pain. Doesn't feel well, sent home from work. Wheezing, stomach pain, diarrhea. Advised to see PCP.

Other Meds: accutone

Lab Data:

History: 7/17/09 Medical records received DOS 7/13/09 to 7/17/09. Asthma.

Prex Illness: none

Prex Vax Illns: site soreness~HPV (Gardasil)~1~25~Patient

Vaers Id: 351476-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Jul-2009	10-Jul-2009	0	15-Jul-2009	27-Jul-2009	NC		27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Crying, Depressed level of consciousness, Dizziness, Dyskinesia, Fall, Fundoscopy normal, Haemorrhage, Headache, Loss of consciousness, Nausea, Skin laceration, Tachycardia

Symptom Text: Shortly after receiving her Gardasil, patient felt a little bit tachycardic (did not report this until later). She walked up to the desk at the nurse's station to receive her paperwork and stated she felt dizzy. As the nurse at the desk got up to help her, she fell to the floor. She was unconscious at the time. Shortly thereafter she made some purposeless movements of both upper extremeties. Within about 30-60 seconds her movements became more purposeful and she began to speak and cry. BP was 100/50 and pulse was approx 120. We asked if she would like to see her father and she nodded. Dad was found in the waiting room and brought back to where she was lying on the floor. A 1 inch linear laceration was found on her posterior occiput. It bled copiously initially but stopped bleeding within a few minutes. At that point patient was awake and had no complaints of neck pain. She did complain of head pain. Responses at that point were appropriate but a bit slow. We helped patient sit up, and transferred her to a stretcher in an exam room. Fundoscopic exam was normal. She was oriented x3 (and remained so). The initial plan was to clean and close her head laceration and send her for an outpatient CT, but she continued to complain of nausea when she rolled to either side, so we were unable to access the laceration. She tolerated sitting up a little ways. She did try to stand up once about 1 hour after the initial event and took a few steps, and then complained of dizziness and had to sit back down. She was helped back to the stretcher. We decided at that point to transfer her to ED via ambulance.

Other Meds: Hydrochlorothiazide 25MG, 1 tablet BID; Pyridoxine HCl 100MG, 5 Tablet daily; Urocit-K 5 540MG,

Lab Data:

History: Primary Hyperoxaluria

Prex Illness:

Prex Vax Illns:

Vaers Id: 351536-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	20-May-2009	20-Jun-2009	31	16-Jul-2009	27-Jul-2009	AZ		27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Diarrhoea, Dysphagia, Myalgia, Nausea, Pruritus, Pyrexia, Urticaria

Symptom Text: Fever, nausea, diarrhea, itchy Skin/Hives. Joint pain, Myalgia. Trouble Swallowing.

Other Meds: None

Lab Data: None

History: Latex; Erythromycin; Sulfa

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351553-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.9	F	09-Jul-2009	09-Jul-2009	0	16-Jul-2009	27-Jul-2009	FL		27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Vaccine positive rechallenge

Symptom Text: Child almost bumped in the door as she left the office after the 1st GARDASIL and felt dizzy but got betters quick. Today after the 2nd GARDASIL - she got dizzy again and very pale (within minutes of the shot) - she recuperated very quickly with no "LOC".

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns: Dizziness.~HPV (Gardasil)~1~12~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351555-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Jul-2009	09-Jul-2009	0	16-Jul-2009	27-Jul-2009	MA		27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2922AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0192Y	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: Pt received varivax vaccine sc in left arm. Patient was seen in Emergency Room on 07/10/09 for redness at site on left arm. Treated with Keflex. Seen in office 07/11/09 and had an area of redness approx 2.5 cm x 2.5 cm in size.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 351576-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-May-2009	28-May-2009	15	16-Jul-2009	17-Jul-2009	FR	WAES0907USA01218	17-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1401F		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Neuritis, Pain in extremity, Paraesthesia, Vomiting

Symptom Text: Information has been received via an Agency from a physician concerning a 13 year old female who on 13-MAY-2009 was vaccinated IM with GARDASIL (lot# 1401F, batch# NF46010) 0.5mL. On 28-May-2009, the patient experienced neuritis sensory. It was reported that first symptoms (pain and tingling sensation in left arm) occurred 15 days after vaccination (on 28-MAY-2009). The symptoms started after gym class and they were very intense during the night that the patient vomited (considered a symptom of the neuritis). On 03-JUN-2009, during examination there were no signs of pathological changes except pain and tingling sensations in left arm as reported by the patient. The patient had no headache. On 05-JUN-2009, the patient's mother reported by phone that the patient was feeling better and that pain was not so intense any more and that she had no tingling sensations any more. The reporter felt that neuritis sensory was possibly related to therapy with GARDASIL. The reporter considered neuritis sensory to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 351596-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-May-2009	06-May-2009	0	16-Jul-2009	27-Jul-2009	OH		27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	UNKNOWN MANUFACTURER	0932X		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	0050Y		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Muscular weakness, Weight bearing difficulty

Symptom Text: This 15 year old received the following vaccines on 5/6/2009. HPV Lot # 1129X, HAV Lot # 0932X, and Varivax Lot # 0050Y. The primary medical doctor e-mailed me 7/15/09 concerned that the patient had "extreme dizziness and leg weakness a few hours after her 1st Gardasil which recurred the next day and again 6 days later. The leg weakness was significant enough that the patient could not bear weight on the leg. Symptoms resolved. PMH: Pt has mild asthma and allergic rhinitis. Otherwise neg med hx.

Other Meds:

Lab Data: none

History: allergies / rhinitis

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351598-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Jul-2009	07-Jul-2009	4	16-Jul-2009	27-Jul-2009	MI		27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	171SX	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epistaxis

Symptom Text: Mom states that pt had a nose bleed 4 days post gardisil #1. States pt has never had nose bleed int the past "It gushed and woke her up-we got it to stop after a few minutes". States pt had another that day and it gushed while blowing her nose, the third one was scant when she was playing. States no more since then. Denies any othe signg or symptoms. Denies hx of blood/clotting dyscrasia.

Other Meds: none

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351599-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jul-2009	15-Jul-2009	1	16-Jul-2009	27-Jul-2009	FL		27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Headache, Hypersomnia, Injection site pain, Nausea

Symptom Text: My daughter received the HPV Vaccine Gardasil on Tuesday, July 14th at 6pm. On Wednesday July 15th she woke up with pain at the injection site and difficulty breathing. She had this on and off all day. She slept for 6 hours which is highly unusual. Later she experienced a headache and neausea. She is otherwise healthy. This was her second dose and she will not be getting a third. There was no reaction after the first dose.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **351601-1 (S)** **Related reports:** 351601-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Jul-2009	08-Jul-2009	1	16-Jul-2009	21-Jul-2009	IL		17-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB329AA		Right arm	Unknown	
HEP	UNKNOWN MANUFACTURER	0725X		Right arm	Unknown	
VARCEL	MERCK & CO. INC.	03761		Right arm	Unknown	
TDAP	SANOFI PASTEUR	C2825A		Left arm	Unknown	
TD	SANOFI PASTEUR	U2347CA		Left arm	Unknown	
MNQ	SANOFI PASTEUR	U2906AA	0	Right arm	Intramuscular	
MMR	MERCK & CO. INC.	1571X		Right arm	Unknown	
HPV4	MERCK & CO. INC.	0558X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal tenderness, Anaemia, Back pain, Chills, Costovertebral angle tenderness, Disseminated intravascular coagulation, Epistaxis, Headache, Heart rate increased, Hypokalaemia, Kidney infection, Neck pain, Pharyngeal oedema, Pyelonephritis, Pyrexia, Rectal haemorrhage, Sepsis, Thrombocytopenia, Vaginal haemorrhage, Viral infection, Vomiting

Symptom Text: 07-08-2009 Patient came home with chills and fever; started vomiting during night. Fever was up to 103.5. Also had lower back pain and headache. Vomiting and fever continued and went to Dr. on 7-10-2009 and was diagnosed with viral illness and started on antibiotic and compazine. Was admitted to Hospital later that day because of elevated WBC, and was diagnosed with Kidney infection, Sepsis and Disseminated Vascular Deterioration. Was in hospital for 5 days. 7/22/09 Hospital records received DOS 7/11/09 to 7/15/09. Final Diagnoses: Pyelonephritis, Disseminated intravascular coagulation, Hypokalemia, Thrombocytopenia, Acute anemia due to disseminated intravascular coagulation. Patient presented with fever and persistent vomiting. Generalized pain back and neck. Abdominal tenderness and right constovertebral angle tenderness. Heart rate 120. Pharyngeal erythema. Decreased urinary flow. Blood per rectum, vaginal bleeding, nosebleeds. 7/24/09 ICD-9 Codes: 590.80 286.6 287.5 276.8 285.9

Other Meds: None

Lab Data: Elevated WBC and Low platelets. 7/22/09 Hospital records received DOS 7/11/09 to 7/15/09. LABS and DIAGNOSTICS: Urine - E. coli. Blood - E. coli. Urine Dip - 500 leukocyte esterase, positive nitrites, 250 blood. CBC - RBC 3.44 m/uL (L) HG

History: None. 7/22/09 Hospital records received DOS 7/11/09 to 7/15/09. Mono, allergy to Cefaclor.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **351601-2 (S)** **Related reports:** 351601-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Jul-2009	07-Jul-2009	0	23-Jul-2009	24-Jul-2009	--	WAES0907USA02864	24-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2906AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Subcutaneously	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Autoimmune disorder, Chills, Cystitis, Disseminated intravascular coagulation, Escherichia sepsis, Incorrect route of drug administration, Injection site pain, Kidney infection, Malaise, Nausea, Pyrexia, Vomiting

Symptom Text: Information have been received from two registered nurses concerning an 18 year old female with no pertinent medical history who on 07-JUL-2009 was vaccinated with a first dose of GARDASIL (lot# 658271/0558X) via subcutaneous route and MENACTRA (lot#U2906AA) concomitantly at separate injection site. Late on 08-JUL-2009, the patient started having chills; on 09-JUL-2009, the patient developed stomach cramps, vomiting, a fever of 103.5, the patient "was very ill". Her arm was sore at the injection site. The patient visited the doctor on 10-JUL-2009 who gave her "a suppository" and put her on ZOFRAN (GlaxoSmithKline), but "it did not do a thing". That night, the patient went to the emergency room where a virus was suspected; later that night, the patient was admitted to hospital. The patient's condition was "very grave". She was shown to have an increased WBC and falling platelets (laboratory values not available), which "indicated that she was having an auto immune response to vaccine". The patient was put on IV LEVAQUIN (Ortho-McNeil) and IV potassium. Her platelet count started to improve after getting LEVAQUIN. The patient was diagnosed with disseminated intravascular coagulation (DIC). A blood test was positive for e-coli. It was reported that "They are not sure where the e-coli came from, whether or not a vaccine was infected with e-coli." Even though there were no symptoms of a bladder infection, the patient was shown to have had a bladder infection which led to a kidney infection which entered the bloodstream causing sepsis (e-coli). The patient was discharged on 15-JUL-2009. The patient was presently feeling better and had had "no fever for 48 hours". The patient's platelet count was better, and she was still feeling nauseous. There were virus tests done while she was at the hospital, but the results had not come back yet. At the time of reporting, the patient was recovering. The symptoms were considered to be immediately life-threatening and disabling by the registered nurse. A lot check has been requested

Other Meds:

Lab Data: diagnostic laboratory, 07/10?/09, positive for e-coli; temperature measurement, 07/09?/09, 103.5; WBC count, 07/10?/09, showed an increased WBC; temperature measurement, 07/15?/09, no fever; platelet count, 07/10?/09, falling; platelet coun

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351603-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jul-2009	15-Jul-2009	1	16-Jul-2009	27-Jul-2009	WI		27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1187X	1	Left arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB312AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0558X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus

Symptom Text: 2 X 3 inch reddened area on left arm. C/O itching

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 351621-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	10-Jul-2009	11-Jul-2009	1	16-Jul-2009	27-Jul-2009	MO		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Back pain, Dyspnoea, Hypokinesia, Injection site pain, Neck pain, Pain in extremity, Swelling

Symptom Text: Pt received GARDASIL #2 on 7/10/09. No complaints at visit. Phone call to clinic Mon 7/13/09 08:10am. Pt reported to RN pains swelling and unable to move (L) arm, neck (L) side, pain to back area since 7/11/09 sat. Appt @ clinic 7/14/09 Pt states also felt short of breath sat 7/11/09 along with pain back, neck, arm. Shortness of breath went away, + weakness + pain (L) arm + (L) neck. No edema no erythema. Recommended ibuprofen 600g massage, heat.

Other Meds: Prenatal vitamins; CLARITIN; Given Rx for ProAir HFA 7/10/09.

Lab Data: None

History: Irregular menses / self reported: occasional asthma; Infertility; Environmental allergies; weight concern; GI problems.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351706-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	08-Jul-2009	13-Jul-2009	5	17-Jul-2009	27-Jul-2009	NY		14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass, Injection site swelling, Injection site warmth

Symptom Text: After 2nd HPV vaccine 5 days later pt experienced swelling (lump) and hotness at injection site. Recc cold compresses

Other Meds: Nuvanna

Lab Data:

History: healthy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351711-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Jul-2009	08-Jul-2009	1	17-Jul-2009	27-Jul-2009	NE		27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3098AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Mass, Pain in extremity, Swelling

Symptom Text: Pain 24 hours after shot - swelling redness lump under tissue 1.5cm. Cont x 4 days came in - Tx ice to area (5 minutes intervals! and BENADRYL 25mg Q6hrs and TYLENOL for pain.

Other Meds: none

Lab Data:

History: none; history spasmadic bronchitis

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351715-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	19-May-2008	01-Jul-2008	43	17-Jul-2009	20-Jul-2009	MD	WAES0808USA04839	20-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received for the pregnancy registry for GARDASIL from a master of science in nursing concerning a 26 year old female with no pertinent medical history and allergy to erythromycin who on 24-MAR-2008 was vaccinated with the first 0.5mL dose of GARDASIL IM (Lot No. 655604/0052X) and on 19-MAY-2008 was vaccinated with the second 0.5mL dose of GARDASIL IM (Lot No. 660389/1968U). Concomitant therapy included MOTRIN and vitamins (unspecified). The patient received her first two doses of GARDASIL and is now pregnant. The patient sought medical attention, seen by the practice. The last menstrual period was on 01-JUL-2008. On an unspecified date, was performed a urine pregnancy test and a serum pregnancy test resulting positive. Estimated date of delivery approximately on 07-APR-2009. The patient has not experienced any known symptoms. Follow up information has been received from a case manager in the office, concerning a 26 year old female who on 17-FEB-2009 "lost" the baby. However, the mother is fine. The office hasn't really followed her and doesn't have much more information. Upon internal review: the patient "lost" her baby, was considered as other important medical event. No further information is available.

Other Meds: MOTRIN; vitamins (unspecified)

Lab Data: urine beta-human, positive; serum beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 7/1/2008); Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **351718-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-May-2009	25-Jun-2009	28	17-Jul-2009	20-Jul-2009	PA	WAES0907USA01273	02-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	2	Left arm	Intramuscular	FLUN HEPA HPV4 TDAP

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Ear infection, Grand mal convulsion, Loss of consciousness, Otitis externa, Pyrexia, Swollen tongue, Tachycardia, Tongue biting, Unresponsive to stimuli

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter with no medical history and drug allergies, who in approximately "September 2008" was vaccinated with her 1st dose of GARDASIL. The 2nd dose was unspecified. On 29-MAY-2009, the patient received the 3rd dose of GARDASIL, 0.5ml, IM. Subsequently, the patient had a seizure when she was sleeping on 25-JUN-2009. She was sent to ER but was not admitted. There was no concomitant medication. Lab diagnostics studies included EEG, CAT scan, and MRI. The patient had seen a neurologist about the seizure. The patient had recovered from seizure on 25-JUN-2009. Follow-up information had been received through a phone call, a nurse concerning that the patient was vaccinated with her 1st dose of GARDASIL (Lot#660391/0063X) on 16-JUL-2008, concomitantly received ADACEL (lot# C2994AA), HAVRIX (lot# AHAVB235BA), and tuberculin purified protein derivative (PPD) (LOT#C2907BA), results negative. The 2nd dose of GARDASIL (lot# 659184/0843X) was administered on 10-OCT-2008, and concomitant therapy included FLUMIST (lot#50545P). On 28-MAY-2009, the patient received the 3rd dose of GARDASIL (lot# 662300/0100Y), 0.5ml, IM. On 25-JUN-2009, the patient had a seizure and was taken to hospital but not admitted. The patient's CT scan was negative and EEG results were pending. The patient mother felt that the patient's seizure and was taken to hospital but not admitted. The patient's CT scan was negative and EEG results were pending. The patient mother felt that the patient's seizures were linked to GARDASIL vaccinations. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested. 7/21/09 ER records received DOS 6/25/09. Assessment: New Onset Seizure. Parent witnessed patient's seizure in bed. Lost consciousness, unresponsive, confusion. Patient presents with trace swelling of tongue, tachycardia. To have MRI with Gandolinium. 9/11/09 Medical records received DOS 7/16/08 to 7/14/09. General

Other Meds: ADACEL; HAVRIX; FLUMIST; tuberculin purified protein

Lab Data: Computed axial, 06/25/09, negative; Mantoux test, 07/16/08, negative. 7/21/09 ER records received DOS 6/25/09. LABS and DIAGNOSTICS: CBC - WBC 3.6 K/UL (L) PLT 144 K/UL (L). CT Brain - normal, Right sphenoid sinus mucosal thickening noted

History: None. 9/11/09 Medical records received DOS 7/16/08 to 7/14/09. Otitis Externa. Counseling - shyness. Depressed/Social Issues. Febrile Seizures. Varicella 9/18/09 Neurology consult received DOS 7/8/09. Febrile seizures. Falls.

Prex Illness:

Prex Vax Illns:

Vaers Id: 351720-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Mar-2009	10-Apr-2009	11	17-Jul-2009	20-Jul-2009	FR	WAES0907USA01349	20-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	MMR
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pregnancy on oral contraceptive

Symptom Text: Information has been received from the health authorities concerning a 17 year old female who was vaccinated with two doses of GARDASIL (batch# not reported) and two doses of ENGERIX (GlaxoSmithKline) respectively on 30-MAR-2009 and 28-MAY-2009. She had also received two doses of PRIORIX (GlaxoSmithKline) respectively on 23-MAR-2009 and 08-JUN-2009. She became unexpectedly pregnant whereas she was taking YASMIN without oversight, without concomitant treatment and without any episode of diarrhea or vomiting. Her LMP dated back to 17-MAR-2009. Estimated conception date was on 10-APR-2009. Consequently, she received a dose of each vaccine before pregnancy and a dose of each in the "maximal high-risk period of malformation" during pregnancy. To be noted that the Health Authorities considered the case as serious due to the medical ineffectiveness. But according to them, YASMIN was possibly ineffective and possibly related to the event, but the vaccines were not related neither to the medicine ineffectiveness nor to the event. Other business partner numbers included E2009-05798. No further information is available.

Other Meds: ENGERIX-B 28May09; PRIORIX 08Jun09

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 17Mar09)

Prex Vax Illns:

Vaers Id: 351770-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jul-2009	17-Jul-2009	0	17-Jul-2009	27-Jul-2009	OH		28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2937HA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Blood pressure decreased, Convulsion, Feeling hot, Lethargy, Loss of consciousness, Malaise, Pallor, Syncope

Symptom Text: PATIENT CAME TO HEALTH DEPARTMENT FOR COLLEGE IMMUNIZATIONS. NERVOUS ABOUT SHOTS. DETERMINED NEEDED Tdap(FOR COLLEGE ENTRY), MENACTRA, AND GARDASIL (LAST 2 FOR COMPLETE IMMUNIZATIONS SERIES). EXPLAINED SIDE EFFECTS. TDAP GIVEN IN LEFT DELTOID AND GARDASIL GIVEN IMMEDIATELY AFTER IN LEFT UPPER ARM. PATIENT SAID THAT SHE DID NOT FEEL WELL, BECAME PALE AND FAINTED. LOWERED TO FLOOR FROM CHAIR. PALE, AND HAD WHAT APPEARED TO BE A SEIZURE. WITHIN SECONDS WAS TALKING BUT COMPLAINED OF BEING WARM. B/P 72/59 PULSE 84/MIN,NEVER STOPPED BREATHING. 911 CALLED AND RESPONDED B/P INCREASED AND PATIENT SITTING IN CHAIR AND SAYS FEELS BETTER. SHE SIGNED THAT SHE DIDN'T WANT TO GO TO ER AND THEY LEFT. WITHIN ABOUT 4 MINUTES SHE FAINTED AGAIN. LOWERED TO FLOOR AND PATIENT WAS TALKING BUT LETHARGIC. B/P WAS 112/ FIRST RESPONDERS RETURNED AND SITTING IN CHAIR B/P 108/ DRINKING SOME JUICE AND TALKING WITH 1ST RESPONDERS. AFTER APPROX 5 MINUTES WHILE FIRST RESPONDERS WERE STILL HERE SHE FAINTED AGAIN AND APPEARED TO HAVE A SEIZURE. FIRST RESPONDERS LOWERED HER TO FLOOR AND WITHIN SECONDS AGAIN SHE WAS RESPONDING AND TALKING. DECISION TO TRANSPORT TO ER. 7/24/09 ER records received DOS 7/17/09. Final Diagnosis: Vasovagal syncope. Patient reports receiving 2 shots today and passing out before receiving the 3rd. Total of 3 episodes syncope. Anxious. Presents for evaluation of syncope. ICD-9 Codes: 780.2

Other Meds:

Lab Data: 7/24/09 ER records received DOS 7/17/09. LABS and DIAGNOSTICS: EKG WNL. Urinalysis - Cloudy, Leukocytes (+), Epithel. moderate, bacteria many. Amorph 2+.

History: NO. 7/24/09 ER records received DOS 7/17/09. Phobia of needles. would pass out as a child.

Prex Illness: NO.BUT AFTER THE INCIDENT PATIENT SAYS SHE HAS PASSED OUT WHEN SHE HAD SHOTS AS A CHILD AND LAST YEAR PASSED OUT AT SCHOOL AND N

Prex Vax Illns:

Vaers Id: 351774-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	30-Mar-2009	30-Mar-2009	0	17-Jul-2009	27-Jul-2009	WI		28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site pain, Musculoskeletal pain, Nausea, No reaction on previous exposure to drug, Pain in extremity

Symptom Text: Calls to say is declining 3rd Gardasil Still having shoulder pain from 2nd inj. Day of 1st inj and after no sx. 2nd inj: day of inj headache ,nausea, sore arm. Severe pain con't at injection site for 1 wk. If rolled on arm would wake her up do to the pain. If leaned on Rt elbow would get referred pain in rt shoulder and at inj site. Pain intermittently con't in right shoulder and inj site. Feels some of pain is in shoulder Joint. This pain con't thru today though is intermittent. Pt did not seek Tx of any kind and this is the first time she is reporting this to a medical provider. Pt wants adverse reaction form completed. Form found on WIR Web site. Pt understands information will be sent to CDC and FDA where information on adverse Rx form Her identity will be kept confidential. Pt to call back if Sx do not go away. Pt. expresses understanding will follow above plan.

Other Meds: Levothyroxine 150 mcg daily, Celexa 40 mg daily, fish oil, flaxseed oil, evening primrose, multivitamin, and a yeast defense supplement.

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351776-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	14-Jul-2009	14-Jul-2009	0	17-Jul-2009	27-Jul-2009	NY		28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	697AA		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1783X	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B031AB		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0070X		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Rash vesicular

Symptom Text: SEVERAL HOURS AFTER RECEIVING THE VARICELLA VACCINE, THE PATIENT EXPERIENCED BLISTERS ON HER BODY. THE BLISTERS RESEMBLED VARICELLA INFECTION.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351782-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jul-2009	17-Jul-2009	1	17-Jul-2009	27-Jul-2009	PA		05-Jan-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB29AA	0	Right arm	Intramuscular	
HEP	MERCK & CO. INC.	1678X	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	
IPV	SANOFI PASTEUR	B00092	1	Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2826CA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B036BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy, Paraesthesia

Symptom Text: Client had vaccines 7/16/2009. Reports that at 11:30 this am (7/17/09) she started with lower facial tingling and family member says that when the client spoke her lips and lower side of face appeared to be pushed to the right side. Denies any weakness but smile does appear to be lopsided when client returned to clinic today at 3:30 pm. Denies any additional symptoms. Referred to primary doctor and left center at 3:45 pm to see doctor. (Family member made appt. while in office at center 7/17/09) Doctor contacted family for follow-up. Stated that family took pt to doctor on 7/17 and was diagnosed with Bells Palsy.

Other Meds:

Lab Data:

History: NONE KNOWN

Prex Illness: NONE KNOWN

Prex Vax Illns:

Vaers Id: **351793-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	17-Jul-2009	17-Jul-2009	0	18-Jul-2009	28-Jul-2009	FL		28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Diarrhoea, Feeling cold, Hyperhidrosis, Insomnia, Malaise, Nausea, Palpitations, Skin burning sensation

Symptom Text: at 9:00 am I had the 3rd gardasil shot and about 10 minutes later I was feeling sick, nausea,diarriah, stomache pains, insomnia, heart palpatations,feeling like my skin is on fire.sweaty, cold and hot flashes.

Other Meds:

Lab Data:

History: n/a

Prex Illness: anxiety

Prex Vax Illns: stmoache pains~HPV (Gardasil)~3~26~In Patient

Vaers Id: **351795-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jul-2009	16-Jul-2009	0	18-Jul-2009	28-Jul-2009	AR		28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aggression, Confusional state, Convulsion, Crying, Eye movement disorder, Fall, Gaze palsy, Head injury, Headache, Listless, Loss of consciousness, Mood altered, Nausea, Opisthotonus, Pain, Syncope, Tension

Symptom Text: 2nd dose of gardasil administered in check in room in left upper arm. Allowed to go, walked around the corner to check out and my daughter's eyes rolled back in her head and she began falling backwards. As she fell, her arms were drawn into her chest and her back was arched. She hit the floor full force on the back of her head and her hands remained tensed and pulled to her chest and her eyes began moving back and forth rapidly and then went back into her head again. Her pulse at this time was 62. She was in a total state of confusion once she regained consciousness and was very listless. A dr began asking her questions which she was unable to answer some of. No one checked her pupils with light. An ambulance was called from the hospital adjacent to the clinic and she was admitted to the ER. For the first 30-45 min in the ER she cried uncontrollably from the pain and her mood took an agressive turn. Her blood sugar was checked and an attempt to give her tylenol by mouth was made but she was combative and would not take it. She was taken to have a CT scan and returned. The CT came back normal and urine and blood were checked. We were discharged with a diagnosis of vasovagal syncope. My daughter had a seizure and not just a fainting spell. I witnessed the drawing up of the arms and the eye movements. I honestly thought she was dieing right there in from of me. She is a VERY healthy child involved in sports with no history of fainting or seizures and none in our family. As of today, she is still suffering from a severe headache and nausea so I would not be able to say she has recovered.

Other Meds:

Lab Data: CT scan, blood sugar level (84), blood and urine taken (not sure what was checked)

History: None

Prex Illness: None

Prex Vax Illns: soreness at injection site and headaches~HPV (Gardasil)~1~14~In Patient

Vaers Id: 351863-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Feb-2007	01-Oct-2007	234	20-Jul-2009	21-Jul-2009	FR	WAES0907USA02141	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1536F	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acne, Amenorrhoea, Concussion, Contusion, Dizziness, Excoriation, Fall, Hyperandrogenism, Hypoglycaemia, Multiple injuries, No reaction on previous exposure to drug, Pallor, Polycystic ovaries, Syncope, Weight increased

Symptom Text: This case was received from a health care professional on 10-JUL-2009. An epicrisis written by the patient's parents, one report on finding from an OPD and one hospital report was forwarded. Information has been received from a general practitioner concerning a 15 year old female who on 09-AUG-2007, was vaccinated with a third dose of GARDASIL (injection site and route not reported, lot number 1536F, batch number NF35190). In October 2007, the patient developed amenorrhea, since February 2008, her weight increased remarkably (up to 18kg until August 2008) and since August 2008, she experienced relapsing dizziness and syncope. Since May 2009, syncope reappeared, followed by falls and several injuries such as costal contusion abrasions and commotion cerebri. The patient was hospitalized from 16-SEP-2008 until 22-SEP-2008. The diagnoses were hyperandrogenemia in the scope of polycystic ovarian syndrome with secondary amenorrhea, reactive postprandial hypoglycemia, neurocardiogenic syncope and acne comedonal. Examination showed increased weight of 70Kg at a length of 169cm. Further physical examination was normal. Blood sample at admission day showed increased AP with 142U/L (normal range 47-119 U/L), hormonal analysis showed increased values of testosterone with 3.62 mmol/L (normal range 0.5 - 2.6 mmol/L), increased androstendion with 4.63ng/mL (normal range 0.55-2.0ng/mL) and 17-OH pregesteron with 6.76 g/L (normal range < 2.0g/L). Therefore treatment with metformin was recommended. The patient experienced syncope for a few seconds during the tilting table test and previous nitroglycerin administration. Thyroid and abdominal sonography, ENT examination, ECG, prolonged blood pressure measurement and cranial MRI showed normal results. A dermatologic examination showed severe acne comedonal of face, chest and back. Treatment with benzoyil peroxide and differine was recommended. The oral glucose tolerance test showed a minimal blood sugar of 48mg/dL within three hours. This result was discussed to be a cause for the oc

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 16Sep08, 4.63 ng/mL, androstendion: increased; ultrasound, 16Sep08, thyroid and abdominal: normal; ears, nose, and throat examination, 16Sep08, normal; magnetic resonance imaging, 16Sep08, Cranial: normal; blood

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **351864-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Sep-2008	24-Sep-2008	0	20-Jul-2009	21-Jul-2009	MI	WAES0810USA02010	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse for the pregnancy registry for GARDASIL concerning a 16 year old female who on 24-SEP-2008 was vaccinated with a first dose of GARDASIL 0.5 ml IM. Subsequently, the patient was found to be pregnant. On 10-OCT-2008 the patient was 6 weeks gestation. The last menstrual period was approximately 29-Aug-2008. The estimated due date is 05-Jun-2009. The patient sought medical attention by calling the nurse. Follow-up information was received from another registered nurse who reported that the patient was vaccinated with a first dose of GARDASIL (lot# 660616/0570X) 0.5 ml IM on 24-SEP-2008. Concomitant therapy included prenatal vitamins (unspecified). At the end of September 2008 or beginning of October 2008, the patient underwent a routine ultrasound without result provided. At the end of November 2008, after Thanksgiving, the patient experienced spontaneous abortion (less than 20 weeks). The outcome of the patient was not reported. Upon internal review the spontaneous abortion was considered to be an other important medical event. Additional information is not expected.

Other Meds: Vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 8/29/2008)

Prex Vax Illns:

Vaers Id: 351865-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	27-Jun-2009	27-Jun-2009	0	20-Jul-2009	21-Jul-2009	FR	WAES0907BRA00015	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0739X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Dyspnoea, Erythema, Inappropriate schedule of drug administration, Oedema peripheral, Pruritus

Symptom Text: Information has been received from a 28 year old female who on 27-JUN-2009 was vaccinated with GARDASIL (LOT # 0739X) (inappropriate age at vaccine administration). Concomitant therapy included Hep A and Hep B vaccines (Manufacturer unknown). On 27-JUN-2009 the patient experienced breathing difficult due to strong pain on chest and swelling on the right hand fingers. On 28-JUN-2009 the patient experienced swelling, redness and itchy on the right foot. On 29-JUN-2009 the patient recovered from strong pain on chest, breathing difficult and swelling on the right hand fingers. As of 29-JUN-2009, the patient was recovering from swelling, redness and itchy on the right foot. The reporter also informed she went to an ER and was placed on therapy with an unspecified IV antiallergic and sodium chloride solution. Upon internal review, chest pain, dyspnea, edema, pruritus, right foot swelling and erythema were determined to be an other important medical event. No further information is available.

Other Meds: Hepatitis A virus vaccine (unspecified), Unk - Unk; Hepatitis B virus vaccine (unspecified), Unk - Unk

Lab Data: Unknown

History:

Prex Illness: Prophylaxis

Prex Vax Illns:

Vaers Id: **351866-1 (S)** **Related reports:** 351866-2; 351866-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Jun-2009	04-Jun-2009	0	20-Jul-2009	21-Jul-2009	NE	WAES0907USA01994	16-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Abdominal distension, Abdominal pain, Abdominal tenderness, Adjustment disorder, Adverse drug reaction, Analgesic intervention supportive therapy, Arachnoid cyst, Arthralgia, Back pain, Blindness transient, Blood glucose decreased, Blood glucose increased, Chest pain, Diplegia, Generalised anxiety disorder, Headache, Hyperhidrosis, Hypertension, Muscular weakness, Musculoskeletal chest pain, Musculoskeletal stiffness, Nausea, Pain in extremity, Reflex test normal, Sinusitis, Somatisation disorder, Swelling, Urticaria, Walking aid user

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 25-JUL-2007 was vaccinated with the first dose of GARDASIL (dose, route and lot # not reported). The patient received the second dose of GARDASIL on 07-FEB-2008 and then received her third dose of GARDASIL on 04-JUN-2009 (dose, route and lot # not reported). The physician reported that on 24-JUN-2009 the patient started to experience painful legs and then on 26-JUN-2009 the patient was unable to walk and by 28-JUN-2009 the patient was walking again. The physician reported that the patient was sent to hospital but it was not specified if the patient was admitted or if she was how long she was in the hospital. At the time of reporting, the patient was recovering. Unable to walk and painful legs were considered to be disabling. Additional information has been requested. 8/31/09 Hospital records received DOS 6/24/09 to 6/28/09. Assessment: Thoracic spine arachnoid cyst without compression of the spinal cord. Lower extremity weakness and pain, cause undetermined. Patient presented with 1-day history of leg pain which started in her knees, went downward, and then began to ascend to chest, back, and lower trunk. Administered pain medications. Neck stiff, rib tenderness. Nausea after Demerol. Hives and swelling with Fentanyl, codeine and morphine have caused nausea and hypertension. Unable to walk on admission. Abdominal distention. Tender to superficial palpation of abdomen, trunk, and lower extremities. Headache. Adjustment disorder, somatization, generalized anxiety. Much improved and discharged. 10/13/09 ICD9 codes received: 729.89, 729.5, 309.4, 349.2, 493.90, V145, 754.79 10/23/09 Discharge Summary, Medical records, vaccine records and ICD9 Codes received for 06/24-9/26. Final DX: Thoracic spine arachnoid cyst without compression of spinal cord, Lower extremity weakens and pain, cause undetermined. Presented in the ED on 6/24 with c/o of lower extremity pain starting at the knees descending, and alternately as

Other Meds: Unknown

Lab Data: Unknown. 8/31/09 Hospital records received DOS 6/24/09 to 6/28/09. LABS and DIAGNOSTICS: CSF - WNL MRI Spine - Abnormal. Chest X-ray - Normal. EKG - Normal. CBC - Unremarkable. Metabolic Panel - Unremarkable. ESR - Pending. ANA - Pending.

History: Unknown. 8/31/09 Hospital records received DOS 6/24/09 to 6/28/09. Mosquito bites. Clubfoot surgery.Allergies: Fentanyl, sulfa, Ceclor, nickel, codeine, Demerol. PMH:Family h/o migraines, seizures, MI, CA.

Prex Illness:

Prex Vax Illns:

Vaers Id: **351866-2** **Related reports:** 351866-1; 351866-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Jun-2009	25-Jun-2009	21	25-Aug-2009	02-Sep-2009	NE		02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Neurological symptom

Symptom Text: Mother called in for vaccine lot. Today reports onset neurological s/s 3 wk post infection. Has followed with Dr. 08/21/09.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **351866-3** **Related reports:** 351866-1; 351866-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Jun-2009	23-Jun-2009	19	19-Oct-2009	27-Oct-2009	NE		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Areflexia, Blepharospasm, Blood glucose decreased, Bone pain, Chest discomfort, Drug hypersensitivity, Gait disturbance, Headache, Muscle spasms, Muscle swelling, Muscle tightness, Neuralgia, Neurological symptom, No reaction on previous exposure to drug, Pain, Paralysis, Speech disorder, Tremor, Ultrasound scan, Walking aid user, West Nile virus test positive

Symptom Text: Third in series Lot #0653x Manufacturer Merck Did not have any unusual reactions after first two My otherwise healthy, active, athletic 14-year-old daughter has experienced serious neurological symptoms 15 days after her 3rd HPV shot. She was transported by EMS to Hospital after she experienced sudden onset paralysis that began at her feet and rapidly spread to just below her shoulders within 24 hours. You could not touch her anywhere below her chest, as even the slightest touch was excruciatingly painful. Her chest felt as though she had a tight band around it. It was difficult for her to talk, and it became difficult for her to keep them open. Jolts of pain would surge up her spinal cord into her head. Her torso muscles front and back swelled. For three days she could not lift or reposition any part of her body beneath her chest. She lost all reflexes in her legs. On day four, she began to move again - very slowly, very deliberately, with assistance. She was released on day 5, with a walker, anti-inflammatory and anti-depressant medication. It took a total of 10 days and extensive Physical Therapy for her to be able to walk "normal" again. She has seen Neurologists, Neurosurgeons, Pediatricians, Rheumotologists, Internal Specialists, Pediatricians, Physical Therapists, Psychologists, and Social Workers. They have run MRI's, CT's, Ultrasounds, and x-rays. She has had two lumbar punctures (they missed the first time), blood tests, and urine tests. The medical professionals have ruled out Guillain Barre, Epstein Barr, Acute West Nile, Lyme disease, encephalitis, meningitis, muscular dystrophy, multiple sclerosis, and bacterial infection but do not have the slightest idea what is going on! The only abnormal findings include: MRI showed arachnoid cyst with accentrical deviation from T2 to T10, but no impingement or damage noted to spinal cord. This MRI was repeated in October, and has shown no change in size, and shows no compression. The Neurosurgeons felt that the cyst was most likely

Other Meds: None

Lab Data: MRI Spine (twice) - no inflammation; detected an arachnoid cyst - no change in size over 3 1/2 months - probably there since birth MRI Brain - normal CT Chest - inflammation of muscles over left ribcage (these are primarily the muscles th

History: Born with club foot, otherwise healthy, active, athletic - very rarely sick

Prex Illness: None

Prex Vax Illns:

Vaers Id: 351867-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jul-2008	25-Jul-2008	2	20-Jul-2009	21-Jul-2009	--	WAES0907USA02007	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Amnesia, Areflexia, Asthenia, Brain oedema, Confusional state, Demyelination, Disorientation, Dysstasia, Electroencephalogram, General physical health deterioration, Guillain-Barre syndrome, Hypokinesia, Nuclear magnetic resonance imaging abnormal, Presyncope

Symptom Text: Information has been received from a nurse practitioner. The nurse practitioner reported that "she was sent an email by one of her patient's mothers who received it from another mother stated that a 15 year old female patient, who was not patient of the nurse practitioner, on 23-JUL-2008 was vaccinated with the first dose of GARDASIL and then two days later the patient almost passed out and was weak for hours. Through the rest of the summer and school year the patient complained that she could not run as fast and was weak. Then on October 17, 2008 the patient received her second dose of GARDASIL and on October 21st the patients mother received an urgent message from the school nurse to take her daughter immediately to her pediatrician. The patient was experiencing confusion, was disoriented, barely could stand, had no reflexes in her feet, and couldn't remember anything that happened that day. The patient was then taken to her pediatrician's office who advised her to see a neurologist. A week later when she saw the neurologist they did a EEG and a MRI because they thought she had a brain tumor, and the patients memory was slowly coming back. Then a second MRI was done which showed she had a demyelination that usually occurs either with GUILLAIN BARRE or with multiple sclerosis. Then later on the patient was diagnosed with GUILLAIN BARRE. The patient was given a spinal tap which showed no permanent damage, inflammation of her brain is going down, she has no debility". GUILLAIN BARRE was considered to be disabling by the nurse practitioner. Additional information has been requested.

Other Meds: Unknown

Lab Data: spinal tap, no permanent damage

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351868-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		20-Jul-2009	21-Jul-2009	FR	WAES0907USA02131	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Areflexia, Hypoaesthesia, No reaction on previous exposure to drug, Nuclear magnetic resonance imaging normal, Pain in extremity, Paraesthesia, Paresis, Pelvic pain

Symptom Text: Information has been received from a health care professional concerning an 18 year old patient who was vaccinated with a third dose of GARDASIL (lot # not reported), site and route not reported on an unspecified date. About 4 weeks p.v. the patient experienced paresthesia of the left thigh, hypalgesia in the supply area of lumbar vertebra 3 (L3) left, paresis of M. quadriceps and M. psoas left with loss of the reflex of M. quadriceps and pain of the pelvis minor and left leg. MRI was carried out and showed normal results. Further neurological investigations were planned. Previous doses of GARDASIL were well tolerated. Paresis, hypalgesia, paresthesia of the lower limb and pain were determined to be an other important medical event. Other business partner's numbers included: E2009-05865. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: 351869-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Nov-2008	04-Nov-2008	0	20-Jul-2009	21-Jul-2009	FR	WAES0907USA02138	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abasia, Abdominal pain, Arthralgia, Fall, Injected limb mobility decreased, Limb injury, Nausea, Pain in extremity, Paraesthesia, Swelling, Ultrasound scan normal, Vaccination complication

Symptom Text: Information has been received from a health authority concerning a 15 year old female with no medical history who was administered on 04-NOV-2008 a dose of GARDASIL (batch number not reported) by intramuscular route (site of administration not reported). It was reported that on the 11-NOV-2008 the patient visited the paediatrician because she had not been able to move her right arm since vaccine administration; her condition has worsened progressively until she'd experienced pain during finger movement. The patient had been to the hospital where she was diagnosed with a postvaccination brachialgia. On the 26-NOV-2008 a sonogram was performed, results were normal. According to a follow up included in the health authorities report (exact date not reported), it has been informed that the patient presented with nausea and abdominal pain on the 09-JAN-2009. It was reported that on the 15-FEB-2009 the patient fell from a staircase with a resulting superficial arm traumatism. On the 20-FEB-2009 the patient started with paresthesia and tingling sensation in hands. By the 27-FEB-2009 the patient had a left hemifacial paresthesia and polyarticular pain. Finally on the 09-MAR-2009, the patient entered the doctor's office with the use of crutches; she was unable to walk because of knee and foot pain with tumefaction. The patient was referred to hospital. Outcome has not been reported for these events. "The CA has only coded the final diagnoses, brachialgia, the other manifestations were mentioned in the narrative field and have been added according to the general coding rules". Case reported as serious by the HA with other medically important condition as criteria. Other business partner's numbers included: E2009-05818 and ES-AGEMED-621215241. Additional information has been reported.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351876-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2009	01-Feb-2009	31	20-Jul-2009	21-Jul-2009	FR	WAES0907BRA00033	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Infectious mononucleosis

Symptom Text: Information has been received concerning a female who in January 2009, was vaccinated with GARDASIL. In approximately February 2009, the patient experienced mononucleosis and was hospitalized during 10 days. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **351904-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Jul-2009	14-Jul-2009	1	20-Jul-2009	29-Jul-2009	NE		29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2822AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	UF484BA	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0593Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Myalgia, Nausea, Syncope

Symptom Text: Myalgias, nausea, episode of fainting the following day, 7/14/09.

Other Meds:

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351918-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-May-2009	Unknown		20-Jul-2009	29-Jul-2009	IN		29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0339Y	0	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2911AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2831AA		Right arm	Intramuscular	
	DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC14B073AA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: none

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351925-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Jul-2009	20-Jul-2009	0	20-Jul-2009	29-Jul-2009	OH		29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2727AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Client received a Menactra on 7/20/2009. She had a previous meningitis vaccine (type/ brand unknown) on 8/23/2007 in another county.

Other Meds: None

Lab Data:

History: NKA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **351942-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Jul-2009	Unknown		20-Jul-2009	29-Jul-2009	IL		18-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0558X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2877AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Patient here for physical with foster mom (her aunt). Denied sexual activity; LMP 6/20/09. Office protocol is to do a preg test if receiving HPV. HepA, MCV4 & HPV given before (+) preg test noted.

Other Meds:

Lab Data: Positive pregnancy test

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 351970-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
37.0	F	08-May-2009	22-Jun-2009	45	21-Jul-2009	23-Jul-2009	--	WAES0907USA01529	09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: DIED, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT AIDS encephalopathy, Acute respiratory failure, Aphasia, Blood pressure fluctuation, Brain death, Brain herniation, Brain oedema, Cerebrovascular disorder, Condition aggravated, Confusional state, Death, Drug abuse, Dysarthria, Encephalitis, Endotracheal intubation, Facial palsy, HIV infection, Heart rate irregular, Hypoaesthesia, Hyporeflexia, Hypoxic encephalopathy, Kidney fibrosis, Lymphadenopathy, Meningeal disorder, Meningitis, Mental status changes, Migraine, Pleocytosis, Pulmonary congestion, Pupil fixed, Spinal cord disorder, Unresponsive to stimuli, Vasculitis cerebral

Symptom Text: Information has been received from an investigator concerning a 37 year old female with HIV and a history of migraine headaches and methamphetamine abuse for 20 years who entered a study. On 08-MAY-2009 the patient was enrolled in A5240 and vaccinated IM with the first dose of GARDASIL, 0.5ml, in deltoid. On 22-JUN-2009 the patient developed the following adverse events: altered mental status grade 3 (dysarthria, anomia, confusion); headache grade 3 (presented to HD 22-JUN-09 with AMS, HA). CT angle of head showed diffuse cerebral edema); left hand numbness grade 2. On 02-JUL-2009 the patient developed decreased neurological reflexes grade 4 (life threatening), pupils fixed and dilated bilaterally grade 4 (life threatening), and death. The report was as follows: The patient presented to emergency department on 22-JUN-2009 with migraine-like headache, left hand numbness, dysarthria and anomia. CT read as normal, patient discharged, the patient returned on 23-JUN-2009 with persistent headache, anomia. At that time, she was not on treatment for HIV and her CD4 count was 263. She was admitted to the neurology service and empirically treated with antibiotics for bacterial and HSV meningitis. Lumbar puncture showed borderline low glucose, elevated protein and a lymphocytic pleocytosis without red blood cells, CSF tests for EBV, HSV, VZV, Cryptococcus, VDRL, AFB smear were negative as well as CSF culture for bacteria, fungus and mycobacteria. CSF cytology was negative, flow cytometry was not performed. JC virus PCR was ordered, but results not reported. Toxoplasma IgG was negative. Blood cultures, coccidioidomycosis titers, serum cryptococcal antigen, RPR were all negative. Prior quantiferon testing in 2004 was positive without subsequent isoniazid treatment chest X ray during admission was negative as were 2 sputum for AFB smear and culture. MRI showed diffuse cerebral edema with leptomeningeal enhancement. Repeated lumbar puncture showed normalization of glucose. During the hospitalization, her symptoms had improved.

Other Meds: None

Lab Data: head computed axial tomography, 06/22/2009, see narrative; spinal tap, 06/23/2009, see narrative; spinal tap, 06/23/2009, normalization of glucose; magnetic resonance imaging, 06/23/2009, brain: see narrative; head computed axial tomography

History: Migraine; Amphetamine abuse; Bell's palsy

Prex Illness: HIV infection

Prex Vax Illns:

Vaers Id: 351972-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Nov-2007	07-Dec-2007	24	21-Jul-2009	22-Jul-2009	GA	WAES0907USA01998	23-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Areflexia, Arthralgia, Asthenia, Back pain, Cough, Dehydration, Dyspnoea, Ear pain, Fall, Fatigue, Gait disturbance, Headache, Hyporeflexia, Joint swelling, Leukopenia, Muscular weakness, Oropharyngeal pain, Otorrhoea, Pain, Pain in extremity, Pain in jaw, Paraesthesia, Peroneal muscular atrophy, Pharyngitis, Photophobia, Positive Rombergism, Pyrexia, Rash, Reflexes abnormal, Swelling, Tooth impacted, Tympanic membrane disorder, Urinary tract infection, Viral infection, Vision blurred, Visual impairment, Weight decreased

Symptom Text: Information has been received from a consumer concerning a 14 years old female with a history of tubes in ears when little and adenoids removed at age 2 years old and no drug reactions who on 13-NOV-2007 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. The patient received the 2nd dose of GARDASIL on 16-JAN-2008 and the 3rd dose of GARDASIL on 23-MAY-2008. At the beginning of February 2009, the patient experienced weakness, pain, tiredness, terrible leg pain, shortness of breath, muscle weakness, every now and then the stomach bothers her, fever, and headache. The patient had been seen in the office and hospitalized. The patient has been in and out of the hospital. The unspecified physicians at the hospital thought the patient had Guillain Barre but later determined it is not. Two spinal taps, 3 CT scans, MRI, numerous X-rays and blood panels were performed. The results showed that there was protein in the spinal fluid. The patient is better but every now and then there is muscle weakness and joint pain throughout both arms, both legs and both feet. The patient was homebound for the rest of the school year and missed school from February to March in 2009. The patient was at the hospital with 17 different physicians. Weakness, pain, tiredness, terrible leg pain, shortness of breath, muscle weakness, stomach bothers her, fever, headache and joint pain throughout both arms, legs and feet were considered to be disabling and immediately life-threatening. Follow-up information has been received from a medical assistant concerning a 14 years old female who on 13-NOV-2007 was vaccinated with the first dose of GARDASIL (lot# 657737/0522U). The patient received the 2nd dose of GARDASIL (lot# 657737/0522U) on 16-JAN-2008 and the 3rd dose of GARDASIL (lot# 658094/0524U) on 23-MAY-2008. No other vaccines were administered at the time of the GARDASIL dose. A lot check has been initiated. Additional information has been requested. 7/24/09 MR received from PCP from 11/2007 to 4/13/09. In f

Other Meds: None

Lab Data: Spinal tap, there was protein in the spinal fluid. 8/6/09 Multiple hospital inpatient, DC summary, and ER records. LABS and DIAGNOSTICS: CBC - WBC 2.61 K/mm3 (L) Mono 14% (H). Urinalysis - protein trace, blood trace, WBC 6 /hpf (H), RBC 13

History: Ear tube insertion; Adenoidectomy. 8/6/09 Multiple hospital inpatient, DC summary, and ER records. Ear infection, tonsillectomy, adenoidectomy. Recent URI. PMH: Pharyngitis. OM. Diarhea. HSV1. Hand pain. weight gain. Dysthymic disorder . Ear tubes. Family hx of CMT.

Prex Illness:

Prex Vax Illns:

Vaers Id: 351973-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Jul-2008	07-Aug-2008	16	21-Jul-2009	22-Jul-2009	FR	WAES0907USA02419	22-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Depression, Emotional disorder, Folliculitis, Seborrhoeic dermatitis, Vaccination complication

Symptom Text: Initial information has been received from a health authority an agency (reference # ES-AGEMED-421214341) via Sanofi Pasteur concerning a 15 year old female patient who on 22-JUL-2008 was vaccinated with a dose of GARDASIL (Lot # and site not reported) IM. It was reported that 16 days after vaccine administration, on 07-AUG-2008, the patient was diagnosed with a pubic area folliculitis, which became generalized by November 2008, microbial and mycological test were performed (date not reported) with negative results. On 24-NOV-2008, the patient developed seborrheic dermatitis accompanied with hair loss. On 02-FEB-2009 (reported as 02-FEB) and 24-FEB-2009 (reported as 24-FEB) the patient visited her general practitioner due to emotional disturbance episodes, on 05-MAR-2009, the patient was diagnosed with a depressive reaction. TRYPTIZOL was prescribed (start and stop dates not reported), the patient did not tolerate this medication so it was changed to ESERTIA. The reporter indicated GARDASIL vaccination complication as a possible diagnosis. The health authority coded seborrheic dermatitis, depression and folliculitis as the only adverse events in the AE field. The rest of the events reported such as hair loss, emotional disturbance and depressive reaction, vaccination complication have been mentioned in the narratives of this case. Case reported as serious by the HA with other medically important condition as criteria. Laboratories performed: on 10-Sep-2008 bacterial test: negative results. On 22-Dec-2008, serum calcium test 10.5 mg/dl. On 22-Dec-2008, serum immunoglobulin E test 7.3 mg. On 22-Jan-2009, blood glucose test 82 mg. On 19-Feb-2009, serum calcium test 9.9 mg/dl. On 05-Mar-2009, serum 25-hydroxyvitamin D2 test 16.1 mg. On unknown date, microbial test: negative results and mycological test: negative results. Other business partner numbers include: E2009-05929. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 10Sep08, bacterial: negative results; Diagnostic laboratory test, microbial: negative results; Diagnostic laboratory test, mycological: negative results; Serum calcium, 22Dec08, 10.5 mg/dl; Serum immunoglobulin E

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351974-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Jan-2009	05-May-2009	118	21-Jul-2009	22-Jul-2009	FR	WAES0907USA02417	22-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Diplopia, Influenza like illness

Symptom Text: Information has been received via a health authority concerning a 17 year old female patient who was vaccinated with a second dose of GARDASIL (lot #, injection route and site not reported) on 08-APR-2009. On 05-May-2009, the patient developed diplopia. Acute disseminated encephalomyelitis was diagnosed by MRI. At the time of reporting, the patient had not recovered. Two weeks after first dose of GARDASIL, administered on 07-JAN-2009, the patient developed flu-like infection. The health authority considered acute disseminated encephalomyelitis to be an other important medical event. Additional information has been requested. Other business partner numbers include E2009-05904, PEI2009014898 and E2009-05903.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, acute disseminated encephalomyelitis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351975-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		21-Jul-2009	22-Jul-2009	PA	WAES0907USA02337	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Epilepsy

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). The physician mentioned that a patient's mother told him that a magazine had an article which stated that a female had a seizure after receiving GARDASIL. She was later diagnosed with epilepsy. The physician stated he had not seen the article and that he was not familiarized with the magazine. Upon internal review, epilepsy was determined to be an other important medical event. Attempts are being made to verify the existence of an identifiable patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 351976-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Feb-2009	03-Feb-2009	0	21-Jul-2009	22-Jul-2009	FR	WAES0903USA03078	22-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0779X	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, Haematoma, Idiopathic thrombocytopenic purpura, Petechiae, Pyrexia, Thrombocytopenia

Symptom Text: Information has been received from a Health Authority (case # 95340) through (local case # IT074/09). Initial report received on 25-FEB-2009. An 11 year old female was vaccinated on 3-FEB-2009 at 4:03 pm with the second dose of GARDASIL (batch number NJ36070, IM, lot number 0779X). On the same day at about 4:30 pm, she presented with scattered petechiae on the upper and lower limbs, transient low grade fever and transitory dyspnea. The duration and outcome were not reported. Case closed. Follow up received on 08-JUL-2009 from Health Authority. On 06-FEB-2009, the patient was hospitalized in the Hematology / Pediatry department for serious thrombocytopenia at 11000 platelets/mm3, petechiae and lower limbs hematoma. WERLHOF disease was diagnosed after bone marrow punction and corticosteroids were prescribed. The patient received treatment with 4 vials of UGOROL, URBASON 360 mg intravenously and ZANTAC 300 mg. Discharge work up showed leukocytes at 16200 (unit not specified); Hemoglobin at 13.6 g/dL, Blood platelets at 119000 (unit not specified). On 24-APR-2009, the patient still received corticosteroid treatment. This case was reported as non serious by Health Authority on 25-FEB-2009. It was upgraded from non serious to serious on 13-JUL-2009 because follow up information specified that the patient was hospitalized. Other business partner numbers include E-2009-01650. The case is closed. No further information is available.

Other Meds: Unknown

Lab Data: WBC count, 06?Feb09, 16200, Discharge work up; hemoglobin, 06?Feb09, 13.6 g/dL; platelet count, 06Feb09, 11000 platelets/mm3; platelet count, ??Feb09, 119000

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 351977-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Mar-2008	Unknown		17-Jul-2009	19-Aug-2009	--	WAES0804USA01770	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Muscle spasms

Symptom Text: Information has been received from a consumer for the Pregnancy Registry for GARDASIL concerning her 18 year old daughter who on 24-MAR-2008 was vaccinated with her first dose of GARDASIL (lot# not reported) and was pregnant. The patient's estimated LMP was 09-FEB-2008. The pregnancy was confirmed with a pregnancy test. The patient sought unspecified medical attention and the physician's information was not available. Follow-up information has been received from a Certified Medical Assistant, who reported that their office did not have any records of the patient receiving GARDASIL injections. In follow-up, the Certified Medical Assistant indicated that on 04-NOV-2008 the patient delivered a normal, healthy male baby weighing 8 pounds, 11 ounces via vaginal delivery. The patient had no complications in her pregnancy, just some "muscle spasms". There was no indication that there were any problems with the baby either. The mother returned for her postpartum exam on 19-DEC-2008 and had a full normal exam and had an intrauterine device (IUD) inserted for contraception. The Certified Medical Assistant contacted during telephone follow-up could not supply the following information: lot number, healthcare provider name and contact information. No further information is available at this time. No further information is available at this time.

Other Meds: Unknown

Lab Data: Physical examination, 12/19/08, postpartum exam: full normal exam; Beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 2/9/2008)

Prex Vax Illns:

Vaers Id: 351978-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Apr-2008	01-Dec-2008	244	21-Jul-2009	22-Jul-2009	FR	WAES0907USA02144	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Systemic lupus erythematosus

Symptom Text: Information has been received from a health authority (ref.#: NL-LRB-88950) concerning an adult female patient who had received a third dose of GARDASIL (batch# not provided). It was reported that she had received GARDASIL according to the schema; she had no complaint after the first and the second dose. She developed symptoms shortly after the last injection. She has systemic lupus erythematosus since December 2008: this appeared 2 months after the last dose and 8 months after the first injection. The patient was admitted to hospital and treated with prednisolone, CELLCEPT and PLAQUENIL and had not recovered at time of reporting. Concomitant drug: DEPO-PROVERA (150mg every 3 months since February 2003) and ethinyl estradiol (+) levonorgestrel (0.03/0.158mg once a day since July 2002). Patient is form country origin, where SLE (systemic lupus erythematosus) is occurring more frequently. The reporter mentioned as other possible causes: heredity, race. The following event (and latency) was coded in the report received from agency: systemic lupus erythematosus (6 months). Noteworthy: The reporter's "summary" (latency of 2 months after last dose, 8 months after first dose) is in contradiction with the coded adverse event where the "reaction first time" is 6 months. Reporter's "summary" mentions concomitant medication (cfr supra) where as agency "narrativeincludedclincal" mentions that comedication is unknown. Other business partner numbers included: E2009-05867. No further information expected.

Other Meds: DEPO-PROVERA, Feb03 - Cont; ethinyl estradiol (+) levonorgestrel, Jul02 - Cont

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351980-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-May-2008	07-Jul-2008	67	17-Jul-2009	19-Aug-2009	TX	WAES0805USA02346	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from the pregnancy registry for GARDASIL vaccine from an 18 year old female consumer, who started therapy with GARDASIL vaccine "last year". On 01-May-2008 she was vaccinated in the arm with third dose of GARDASIL vaccine. On 12-May-2008, the patient found out she was pregnant, she does not know her exact trimester but does know she's very early in her pregnancy. Unspecified medical attention was sought, but no date of last menstrual period, or due date was reported. Follow-up information has been received from a physician's office concerning the patient's pregnancy outcome. It was reported that on an unknown date the patient delivered prematurely a normal infant weighting 4 lb and 13 oz. No congenital anomalies were noted. The patient's and and baby's final outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 351983-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	25-Apr-2008	25-Apr-2008	0	17-Jul-2009	19-Aug-2009	--	WAES0805USA04045	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaginal haemorrhage

Symptom Text: Information has been received from the pregnancy registry for GARDASIL via a nurse practitioner, concerning a 22 year old female with a history of asthma who on 25-APR-2008 was vaccinated with the first dose of GARDASIL, 0.5 ml, IM, (Lot#659962/1740U). The patient sought unspecified medical attention at the office and had a confirmed pregnancy test. Her last menstrual period was reported as 22-MAR-2008, and her due date is 27-DEC-2008. No other symptoms have been noted. Follow-up information has been received from the nurse practitioner, for GARDASIL, a Pregnancy Registry product. On 25-APR-2008 the patient had urine beta-human chorionic gonadotropin test (ECG) performed which was negative. The reporter noted that the last contact with patient was on 14-MAY-2008, when she called to report pregnancy, 8 weeks gestation. And the patient experienced scant pink vaginal discharge. The patient did not return phone calls on 16, 19, 22-MAY-2008, nor to card sent on 22-MAY-2008. The estimated date of delivery was 28-DEC-2008. The pregnancy outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Beta-human chorionic, positive; Urine beta-human, 04/25/08, negative

History: Asthma

Prex Illness:

Prex Vax Illns:

Vaers Id: 351985-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	15-Oct-2007	07-Jan-2008	84	17-Jul-2009	20-Aug-2009	OK	WAES0807USA04408	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal disorder, Premature labour

Symptom Text: Information has been received from a physician, for the Pregnancy Registry of GARDASIL, concerning a 24 year old female with anxiety and depression and no known allergies who on 15-Oct-2007 was vaccinated with the first dose of GARDASIL. On 14-Jan-2008 the patient was vaccinated intramuscularly with the second 0.5ml dose of GARDASIL (lot number 659055/1522U). Concomitant therapy included WELLBUTRIN. The patient is pregnant. Her LMP was 07-JAN-2008. Due date was 13-OCT-2008. The third dose was not administered. On 14-JAN-2008 the patient was placed on WELLBUTRIN. The patient took WELLBUTRIN for three weeks and then the patient stopped taking it since it was not working. The patient was not experiencing any problems. The patient sought unspecified medical attention via office visit. Follow-up information received from the physician reported limited pregnancy outcome information. On approximately 17-Aug-2008 the patient delivered a baby "at around 32 weeks gestation, almost two months early". The physician did not remember exactly and did not have the patient's chart at her immediate disposal. The physician also followed the baby in her practice. The physician reported " he was now around nine months old and weighed around 15 pounds. He had some failure to thrive issues and had some developmental delays". No further information was provided at this time. Additional information has been requested.

Other Meds: Wellbutrin

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP= 1/7/2008) Anxiety; Depression

Prex Vax Illns:

Vaers Id: **351987-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-May-2008	01-Jul-2008	43	17-Jul-2009	20-Aug-2009	TX	WAES0808USA01387	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received through the Merck pregnancy registry for GARDASIL vaccine from a registered nurse concerning a 20 year old female patient with juvenile diabetes and no known allergies who on 19-May-2008, was vaccinated with the first dose of GARDASIL vaccine (LOT # 658222/0927U) 0.5 ml IM. On 29-JUL-2008, was vaccinated with the second dose of GARDASIL vaccine (LOT # 659653/1448U) 0.5 ml IM. Concomitant therapy included insulin (manufacturer unknown). The patient was now pregnant. The last menstrual period was on 01-JUL-2008. On an unspecified date, pregnancy test was performed and resulted positive. No other symptoms were noted. The patient called the doctor for medical attention. Estimated date of delivery on 07-APR-2009. Follow-up information received from the registered nurse revealed that the patient had delivered a baby boy in March 2009 (exact date not known). She mentioned that the baby did have some "heart trouble"; the patient was told that her baby had a "rapid heartbeat". The baby was treated with INDERAL (additional details not known). The registered nurse reported that the patient was told by her doctor that her baby's rapid heartbeat was related to the patient's juvenile diabetes. It was reported that the patient did continue to wear an insulin pump. The reporter stated that she had seen the baby and he did "look normal". She confirmed that the patient had no congenital anomalies. Additional information was received from the nurse the next day. She reported that the baby was born on 18-MAR-2009. The nurse stated that she had said the baby's heart trouble as a "rapid heartbeat" was listed as an "enlargement heart" and was being treated with INDERAL. She had no further information to provide. This is one several reports from the same source. Additional information has been requested.

Other Meds: Insulin

Lab Data: Beta human chorionic, positive.

History:

Prex Illness: Pregnancy NOS (LMP -7/1/2008); Juvenile diabetes

Prex Vax Illns:

Vaers Id: 351990-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	16-Jul-2008	06-Aug-2008	21	17-Jul-2009	20-Aug-2009	--	WAES0810USA02180	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pregnancy induced hypertension

Symptom Text: Information has been received from a physician for the Pregnancy registry for GARDASIL, concerning a 25 year old female with no drug allergies and no medical history who on 22-Sep-2008 was vaccinated with the second dose of GARDASIL. Concomitant therapy included vitamins prenatal. Subsequently the patient determined to be pregnant. A urine pregnancy test on 07-Oct-2008 was positive. The pregnancy questionnaire was received on 15-Oct-2008, which indicated that the patient had two previous pregnancies and one full term (40 weeks birth) Date of LMP was 06-Aug-2008 and EBD is 13-May-2009. Second dose of GARDASIL was reported as 22-Sept-2008 (lot# 0573X). No history of reported pre-term deliveries, spontaneous terminations, elective terminations, fetal deaths and birth defects. On 07-Oct-2008, the patient was prescribed prenatal vitamins. Follow-up information from a physician revealed that the patient experienced no infections or illness but hypertension (date unknown) during pregnancy. The hypertension was treated with Pro Cardia XL 30mg, oral daily on 05-Jan-2009 (duration not reported). During the patient's pregnancy, she underwent the following diagnostics tests: on 25-Dec-2008, a Quad screen showed a negative result. Ultrasound done on 04-Dec-2008, 08-Jan-2009 and 27-Mar-2009 showed normal results. On 22-May-2009, 41 Weeks from the LMP, the patient delivered a normal, healthy female baby weighing 7 pounds 4 ounces with a length of 18.75 inches. No complication occurred during labor/delivery. The baby had Apgar score of 7/9 and congenital anomalies. Additional information is not expected.

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 12/04/08, normal ; Ultrasound, 01/08/09, normal ; Ultrasound, 03/27/09, normal ; Diagnostic laboratory 12/25/08, Quad screen, negative; Urine beta-human, 10/07/08, positive; Apgar score, 05/22/09, 7/9

History:

Prex Illness: Pregnancy NOS (LMP=8/6/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351991-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Sep-2008	Unknown		17-Jul-2009	20-Aug-2009	CA	WAES0810USA03304	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy

Symptom Text: Information has been received from a medical assistant through the Pregnancy registry for GARDASIL concerning a 17 year old female with no previous pregnancies who on 17-Sep-2008, was vaccinated with the second dose of GARDASIL (lot# 659180/1758U) and then discovered that she was pregnant. There was no concomitant medication. No adverse effects reported. Late last menstrual period 16-Aug-2008. Estimated delivery date 23-May-2009. A routine ultrasound was performed on 15-Oct-2000, which was normal. The patient was placed on prenatal vitamins. The patient did not receive the first 2 doses of HPV at the medical assistant's physician office. Follow up information has been received from the physician who reported that in 2009, the patient experienced mild anemia and was treated with ferrous sulfate 325 mg, daily from 11-Feb-2009 to 17-May-2009. Concomitant therapy during pregnancy included vitamins. On 17-May-2009, the patient delivered a normal female baby, at 39 weeks of gestation. The baby weighed 6 pounds, her length was 10.0 inches, and had on APGAR score of 9/9. There were no congenital anomalies and no complications or abnormalities reported. No further information is expected.

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound 10/15/08 - Normal

History:

Prex Illness: Pregnancy NOS (LMP=8/16/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **351992-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Jul-2009	03-Jul-2009	0	21-Jul-2009	22-Jul-2009	FR	WAES0907RUS00004	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 20 year old female who on 03-JUL-2009 was vaccinated with GARDASIL, 1 dose (total daily dose and duration not reported). On 03-JUL-2009 the patient experienced collapse. On 03-JUL-2009 the patient recovered from collapse. The physician reported that the patient's collapse was considered a serious medical event. The reporter felt that collapse was related to therapy with GARDASIL.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **351993-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
33.0	F	16-Sep-2008	16-Sep-2008	0	17-Jul-2009	20-Aug-2009	FR	WAES0810USA03668	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Failed trial of labour, Inappropriate schedule of drug administration, Premature separation of placenta

Symptom Text: Information has been received from a medical assistant, for the GARDASIL, concerning a 33 year old female who on 16-SEP-2008 was vaccinated with the first dose of GARDASIL (Lot # 660620/0571X). There was no concomitant medication. It was subsequently learned that the patient was pregnant at the time of the above GARDASIL. The IMP was 25-AUG-2008. No adverse effects were reported. The patient sought unspecified medical attention. Follow-up information has been received from a health care professional who reported that concomitant therapy included PRENEXA and that the patient had a history of SINEQUAN use 2 years prior to pregnancy, 25 mg daily for depression. The patient did ultrasound on 21-OCT-2008, which showed estimated date of confinement on 03-JUN-2009 and additional ultrasounds occurred on 14-JAN-2009, 18-FEB-2009 and 14-MAY-2009. The MSAFP Test on 07-JAN-2009 showed negative. The Fetal Non-Stress test 2x per week starting from 32 showed reactive. On 25-MAY-2009 (38 weeks and 6 days from LMP) the patient with no previous pregnancy delivered a normal, healthy male baby weighing 7 pounds 15 ounces, Apgar score was 9/9. There was no congenital anomaly, other complication or abnormality. There were no infections, illnesses, or complications during pregnancy, however during pregnancy, however during labor/delivery the patient experienced failure to progress at 4cm, mild abruption during labor/delivery. No further information is available.

Other Meds: vitamins (unspecified)

Lab Data: fetal nonstress test, 04?/??/09, 2x weeks starting at 32 weeks: reactive; serum alpha-fetoprotein, 01/07/09, negative

History: Depression

Prex Illness:

Prex Vax Illns:

Vaers Id: 351994-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Sep-2008	Unknown		17-Jul-2009	20-Aug-2009	AZ	WAES0810USA05202	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Haemorrhage, Premature labour, Premature separation of placenta, Vaginitis bacterial

Symptom Text: Information has been received from a physician for the Pregnancy Registry for GARDASIL, concerning a 15 year old female with bicornuate uterus and a history of chickenpox as child, on 17-SEP-2008 was vaccinated with a dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient was found to be pregnant. The date of last menstrual period was 01-SEP-2008 and the estimated delivery date is 08-JUN-2009. On 18-OCT-2008, the ultrasound showed that the patient had a bicornuate uterus. Follow-up information was received from the physician concerning the female patient. It was reported that during the pregnancy the patient also take NATELLE as prenatal vitamins. On an unspecified date the patient developed bacterial vaginosis, and on 18-NOV-2007 the patient was treated with FLAGYL 500 mg twice a day for 7 days. On 10-MAY-2008, at 36.5 weeks from LMP, the patient delivered a male baby, weighted 5 pound 6 OZ, APGAR score 7/7. It was reported that the baby was normal with no congenital anomalies. The physician also reported that during the delivery the patient had increased bleeding which was believed to be attributed to a partial placental abruption. Additional information is not expected.

Other Meds: NATELLE

Lab Data: ultrasound, 10/18/08, patient has a bicornuate uterus

History: Chickenpox

Prex Illness: Pregnancy NOS (LMP = 9/1/2008); Bicornuate uterus

Prex Vax Illns:

Vaers Id: **351995-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	25-Apr-2008	20-Aug-2008	117	17-Jul-2009	20-Aug-2009	OR	WAES0811USA03512	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour, Premature rupture of membranes, Small for dates baby, Urinary tract infection

Symptom Text: Information has been received from a healthcare worker concerning a 20 year old female with no known drug reactions/allergies and no pertinent medical history, who on 24-MAR-2008 was vaccinated with the first dose of GARDASIL (Lot #658282/0929U), 0.5ml, intramuscularly, on 25-APR-2008 with the second dose of GARDASIL (Lot #658282/0929U), 0.5ml, intramuscularly and on 25-SEP-2008 with the third dose of GARDASIL (Lot #659184/0843X), 0.5ml, intramuscularly. Concomitant therapy included HAVRIX. The healthcare worker reported that the patient, who received her third dose of GARDASIL on 25-SEP-2008, is pregnant. The last menstrual period was on 20-AUG-2008 and the estimated date of confinement is 27-MAY-2009. The patient experienced abdominal pain and discomfort which led to the diagnosis of pregnancy. The patient sough unspecified medical attention. Follow up information was received from a health care professional concerning a 20 year old female patient with no previous pregnancies or full terms deliveries who on 24-MAR-2008, 25-APR-2008 and 25-SEP-2008 was vaccinated with the first, second and third dose of GARDASIL respectively. Concomitant therapy used during the pregnancy included HAVRIX given on 25-SEP-2008, BACTRIM DS TABLET given on 27-DEC-2008 for a urinary tract infection. It was reported that the patient presented with an urinary tract infection during pregnancy. It was reported that ultrasounds were performed on 07-OCT-2008, 08-NOV-2008 and on 19-NOV-2008 (at 6 weeks 0 days, 12 weeks 3 days and 22 weeks 3 days, respectively). On 22-DEC-2008 a laboratory diagnostic test was performed and it was negative for Down syndrome, open spina bifida and Trisomy 18. It was reported that there were a premature rupture of membranes, preterm labor and short cervix. It was reported that on 03-APR-2009, at 32 weeks and 1 day of gestation, the patient delivered two female twins (ID # 36825, weight 1.660 Kg, the head circumference was 32.5 cm, APGAR score were 8/10 at the first minute and 9/10 at the 5 minute) and (ID # 3682

Other Meds: BACTRIM DS TABLETS

Lab Data: ultrasound, Fetal ultrasound: positive; ultrasound, 10/07/08, 6 weeks 0 days; spotting, pain; ultrasound, 11/19/08, 22 weeks 3 day; anatomy screening; diagnostic laboratory, 12/22/08, negative for Down syndrome, open spina bifida and Trisom

History:

Prex Illness: Pregnancy NOS (LMP = 8/20/2008)

Prex Vax Illns:

Vaers Id: 351996-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	13-Nov-2006	01-Jan-2007	49	17-Jul-2009	20-Aug-2009	CA	WAES0905USA04071	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Migraine

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL, concerning a female who in approximately 2007 was vaccinated with the second dose of GARDASIL. She was pregnant at the time the vaccination was administered. Her last menstrual period was in approximately March 2007. The patient did have her child who is approximately 17 months old currently. Following the birth, the patient received the third dose of GARDASIL. The patient sought medical attention. Follow-up information was received from the nurse. She reported that the patient's baby was healthy and normal. Follow up information has been received from the registered nurse concerning this 25 year old female who was vaccinated with the 1st, 2nd and 3rd doses of GARDASIL (1st lot #653735/0688F, 2nd lot #655165/1425F and 3rd lot #659441/1446U) on 13-NOV-2006, 19-JAN-2007 and 04-JAN-2008 respectively. Subsequently, the patient was pregnant at the time of vaccination. The patient's last menstrual period (LMP) was 02-JAN-2007. Her estimated date of delivery was 09-OCT-2007. It was noted that the patient had one elective termination, one previous pregnancy and one full term delivery. There were no birth defects and no infant complications in her previous pregnancy. On 08-FEB-2007, a urine beta-human chorionic gonadotropin test was performed because the patient missed her period. The test result was positive. It was reported that the patient took IMITREX 100 mg as needed for the treatment of migraines during her first trimester. On 10-OCT-2007, 40 weeks from her LMP, the patient delivered a normal, healthy, female baby. There were no complications or congenital anomalies. The baby weighed 7 pounds, 1 ounce, her length was 10 1/2 inches and her head circumference was 14 inches. There were no complications during pregnancy or labor and delivery. Additional information is not expected.

Other Meds: Unknown

Lab Data: urine beta-human, 02/08/07, positive

History: Termination of pregnancy - elective

Prex Illness:

Prex Vax Illns:

Vaers Id: **351997-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA01687	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscle disorder

Symptom Text: Information has been received from a registered pharmacist concerning a "teenager" female who in February 2008, was vaccinated with the First dose of GARDASIL (Lot not reported). Subsequently the patient experienced "muscle problems". The pharmacist noted that the patient went to see her physician. At the time of reporting the outcome of the patient was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352020-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-Jul-2009	21-Jul-2009	0	21-Jul-2009	30-Jul-2009	NV		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Patient with history of cluster headaches. Recently started on topamax. Headaches controlled. Approximately three minutes after administration of Gardasil vaccine, the patient experienced onset of severe headache

Other Meds: Fioricet, Topamax, Vicodin, hydroxyzine, HCTZ, Synthroid, omiperazole, Atenolol, Yasmin

Lab Data:

History: Cluster Headaches, HTN, Obesity

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352024-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Jul-2009	14-Jul-2009	0	21-Jul-2009	30-Jul-2009	CA		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Immediately after administration of HPV patient fainted. Dr. reassessed patient for injury and reaction. Afterwhich patient was o.k.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **352041-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	15-Jul-2009	16-Jul-2009	1	21-Jul-2009	29-Jul-2009	ND		29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF460BA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0087Y	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0500Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Rt arm-area red-warm-swollen-tender to touch. (varicella like) raised area about size of silver dollar-red area about 3" wide and 4 1/2-5" long- Recommended ice 20 min on-20 min off and Ibuprofen if no relief or s/s increase to see phy. for eval.

Other Meds: None

Lab Data: None

History: Allergy to PNC- beestings (carries EPI-PEN)

Prex Illness: None

Prex Vax Illns:

Vaers Id: 352052-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Jun-2009	26-Jun-2009	0	21-Jul-2009	30-Jul-2009	CA		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness, Syncope

Symptom Text: Pt was given GARDASIL vaccine upon checkout Pt fainted. Lost consciousness for ~ 5 sec. Fell and hit head on floor. Sent to ER for CT scan, IV.

Other Meds: Seasonique

Lab Data: CT head and facial bones(6/26/09), MRI brain (7/14/2009)

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **352062-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Jul-2009	21-Jul-2009	0	21-Jul-2009	30-Jul-2009	CA		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	D051Y	1	Left leg	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	1587X	1	Right leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Vision blurred

Symptom Text: Dizziness with Pt blurring of vision after GARDASIL. Few minutes later. She was short of breath > Briefly.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352063-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-Jul-2009	21-Jul-2009	0	21-Jul-2009	30-Jul-2009	CA		06-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2730AA	0	Left leg	Unknown	
	HPV4	MERCK & CO. INC.	0651X	0	Left leg	Unknown	
	TDAP	SANOFI PASTEUR	C2773BA	0	Right leg	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Fainted briefly after immunization: in this order 1 MENACTRA, 2 ADACEL, 3 GARDASIL. Referred to ER because of continued dizziness.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352064-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Jul-2009	20-Jul-2009	0	21-Jul-2009	30-Jul-2009	WI		21-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	4291719AA		Unknown	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041CA		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Malaise, Pallor

Symptom Text: Patient was given GARDASIL on 7/20/09 at 1430 and seconds later patient stated she was not feeling well and asked for water. Patient then turned pale and and began falling backwards. Patient was on exam table and lowered to pillow - No injury from this. Patient lost consciousness for 30 seconds and then regained consciousness. Patient was given juice and re examined by doctor. Her father picked her up and drove her home. Advised patient if she has any SOB, swelling up tongue or throat call 911.

Other Meds: Sertraline, 50 mg 1.5 take daily

Lab Data:

History: NKDA - No other birth defects/medical conditions I'm aware.

Prex Illness: Syncope

Prex Vax Illns:

Vaers Id: **352079-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Jun-2009	08-Jun-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA01721	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Hypotonia, Pallor, Sensation of heaviness

Symptom Text: Information has been received from a patient's mother concerning an 18 year old female with no allergies who on 08-JUN-2009 was vaccinated with her first dose of GARDASIL. Concomitant therapy included YASMIN. Then within a short time after the first dose the patient's arm felt heavy, her face became pale, her body went limp and her arms and legs were flailing. This only happened for a couple of seconds and then she came to and her color in her face came back. The patient stayed at the office for ten more minutes and was given water and sugar since she had an empty stomach and was then fine to leave. No labs and diagnostic tests were performed. The patient slept the rest of the day, and was fine. No further information is available.

Other Meds: drospirenone (+) ethinyl

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352080-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	02-Jun-2008	Unknown		17-Jul-2009	17-Aug-2009	TX	WAES0906USA01741	17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Human papilloma virus test positive, Injection site pain

Symptom Text: Information has been received from a physician concerning a 25 year old female patient with a history of vaginosis bacterial on 19-MAR-2009 who on 02-JUN-2008 was vaccinated with a first dose of GARDASIL (Lot # not reported). On 07-AUG-2008 she received second dose of GARDASIL (Lot # not reported). On 05-DEC-2008 she received third dose of GARDASIL (Lot # not reported). Recently on unspecified date she had "pap smear" that demonstrated "high risk HPV DNA detected". The physician mentioned that the patient had a "PAP smear" prior to beginning the vaccines and it was negative. As a side note the physician mentioned that the patient complained that the second injection of vaccines was more painful than the first. The patient sought medical attention office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, was negative prior to beginning the vaccines; Pap test, Demonstrated "high risk HPVA DNA detected"

History: Vaginosis bacterial

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352081-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	01-May-2009		17-Jul-2009	20-Aug-2009	PA	WAES0906USA01763	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthritis

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a 0.5 mL dose of GARDASIL, intramuscularly. A month or so ago the patient developed arthritis. The physician discontinued the series after this. The patient sought unspecified medical attention. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352082-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-May-2009	28-May-2009	27	17-Jul-2009	20-Aug-2009	OK	WAES0906USA01774	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a licensed practical nurse concerning a 23 year old female with no medical history and drugs allergies, who in November 2007, was vaccinated with a first dose of GARDASIL. The second and the third dose were given in January 2008 and May 2008 respectively. There was no concomitant medication. On 28-MAY-2009 the patient had an abnormal Pap test. The Pap test revealed "atypical cells of undetermined significance with high risk HPV to include HPV types 16 and 18". The nurse added that this was the patient's first abnormal Pap test. The patient sought medical attention through an office visit. At the time of this report the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Pap test, 05/28/09, atypical cells of undetermined significance with high risk HPV include HPV 16 and 18

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352083-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Dec-2008	09-May-2009	159	17-Jul-2009	20-Aug-2009	NJ	WAES0906USA01895	02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female patient. It was reported that in January 2007 the patient's pap smear was normal and negative for HPV. In March 2008 the patient's pap smear was normal and no check for HPV. In December 2008, the patient got series of GARDASIL. In 09-May-2009, the pap smear revealed low grade cervical Intraepithelial Ceoplasia (CIN) and positive for HPV. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical Smear, 03/??/08, normal ; Cervical Smear, 05/09/09, low grade CIN, HPV positive; Cervical Smear, 01/??/07, normal, HPV negative.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352084-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-May-2009	Unknown		17-Jul-2009	20-Aug-2009	WV	WAES0906USA01909	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a nurse concerning a 11-year-11-month- old female patient who was vaccinated with the first dose of GARDASIL IM 0.5ml about 2 weeks ago on appropriately 27-May-2009. The patient had not had her period since she had been vaccinated. The patient had regular periods prior to receiving GARDASIL. It had been approximately 6 weeks since her last period. The patient had sought medical attention, she called the doctor's office. At the time of report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352085-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	01-Jul-2008		17-Jul-2009	20-Aug-2009	OH	WAES0906USA01913	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthma, Condition aggravated, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning her daughter, an 18-year-old female, who in July 2008 was vaccinated with the first dose of GARDASIL 7-10 days after the dose was given, the patient developed asthma like symptoms and sought medical attention and was treated with oral steroids for 3 months. The patient recovered. In October 2008, the patient was vaccinated with the second dose of GARDASIL. 7-10 days after the dose was given, the patient developed asthma like symptoms again and sought medical attention and had to be treated with steroids for 3 months. Subsequently, the patient recovered again. Prior to the vaccinations the patient did not have asthma symptoms for over 10 years. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352086-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		21-Jul-2009	20-Aug-2009	OH	WAES0906USA01923	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Herpes zoster, Infectious mononucleosis

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with the first and only dose of GARDASIL when she was mildly ill. After the vaccination, the patient got sicker. She was determined to have "Mono" and developed shingles. The patient eventually recovered. The patient had seen the physician for medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Sickness

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352087-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	PA	WAES0906USA02001	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthritis

Symptom Text: Information has been received from a physician who has heard of a couple of female patient's who were vaccinated with dose of GARDASIL. The patient's developed arthritis after getting the dose of GARDASIL. Attempts are being made to obtain and verify additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. This is one two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Mar-2009	01-Mar-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA02050	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Photosensitivity reaction, Rash

Symptom Text: Information has been received from a consumer concerning her "teen" daughter who was vaccinated with three doses of GARDASIL as follows: 1st in January 2009, 2nd in February 2009, 3rd in March 2009. The concomitant medication was unspecified. The patient broke out in a white spotted rash while on vaccination after the 3rd dose. The patient was diagnosed with sun poisoning and recovered in about 2 weeks time. The reporter also noted possible mood changed in the teenager after the series that persisted. At the report time the outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352090-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
71.0	F	06-Jun-2009	06-Jun-2009	0	17-Jul-2009	20-Aug-2009	FL	WAES0906USA02051	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Information has been received from a 72 year old female consumer with blood pressure high, cholesterol and Oesophageal Reflux acid reflux concerning herself who was vaccinated with a dose of GARDASIL instead of the ZOSTAVAX (Merck) by mistake on 06-Jun-2009. Concomitant therapy included Aspirin, Minerals (unspecified), and Vitamins (unspecified), Centrum silver, Fish oil, Calcium citrate and Citracal D, Prilosec, Felodipine, Lipitor and Micardis. The reporter mentioned that she was not experienced any side effects, but was worried and need to know if she needed to be concerned. Unspecified blood work as performed (results not provided). At the report time the outcome was unknown. Additional information has been requested.

Other Meds: Aspirin; Lipitor; Citracal D; Felodipin; Centrum silver; Omega-3 marine triglycerides; Micardis

Lab Data: Diagnostic Laboratory - unspecified blood work, results not provided.

History:

Prex Illness: Blood pressure high; Cholesterol high / Oesophageal Reflux acid reflux

Prex Vax Illns:

Vaers Id: **352091-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Feb-2009	01-Feb-2009	0	17-Jul-2009	20-Aug-2009	VA	WAES0906USA02057	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Chest pain, Dermatitis allergic, Dizziness, Headache, Urticaria

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter with seasonal allergy who in October 2008 was vaccinated with the first dose of GARDASIL, the second dose in December 2008, and the third dose on February 2009. Concomitant therapy included prednisone once daily and triamcinolone acetonide, 0.1 %, twice daily. In February 2009, the patient experienced severe skin allergies and she got hives and blisters all over her body. She was also experiencing severe headaches, dizziness and chest pains. The patient sought unspecified medical attention. There were no laboratory studies performed. At the time of report, the patient had not recovered. Additional information has been requested.

Other Meds: prednisone; triamcinolone acetonide

Lab Data: None

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

Vaers Id: **352092-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	26-Mar-2009	26-Mar-2009	0	17-Jul-2009	17-Aug-2009	AL	WAES0906USA02088	17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0074Y	1	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Headache, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female patient with no pertinent medical history or allergies who on 27-JAN-2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL. On 26-MAR-2009 the patient was vaccinated IM with the second of GARDASIL (lot # 0074Y). On 02-JUN-2009 the patient was vaccinated IM with the third 0.5 ml dose of GARDASIL (lot # 0294Y). There was no concomitant medication. After the patient received the second dose she experienced persistent headaches. At the time of this report, the patient had not recovered. The patient sought medical attention through a phone call. Headaches were considered to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: none

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 352129-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Apr-2008	17-May-2008	32	22-Jul-2009	23-Jul-2009	FR	WAES0907USA02122	23-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Chest pain, Dyspnoea, Fatigue, Headache, Lethargy, Malaise, Menstruation irregular, Pain, Paralysis, Phonophobia, Photophobia, Rash, Vaccine positive rechallenge

Symptom Text: Information was obtained from a regulatory agency via a public case details form concerning a 16 year old female patient who from 15-APR-2008 was vaccinated with GARDASIL (Lot not reported) 2 times. After the 1st dose, the patient experienced headaches, menstrual irregularities, pain, light and noise sensitivity and a rash (legs). After the second dose, the patient experienced paralysis, fatigue, lethargy, extreme pain, not responsive to codeine, headaches, chest pain, breathing difficulties, was seriously ill, rash and was unable to shower without assistance. The patient was admitted to hospital. Her events caused or prolonged inpatient hospitalization. Her mother had ceased employment to care for her daughter. Her daughter had missed 70% of school in the past 6 months and it was noted that her symptoms were episodic. At the time of report on 15-JUL-2009, the patient had not yet recovered and her care was still ongoing. The agency considered that all the symptoms were possibly related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352131-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Jan-2009	16-Jan-2009	8	22-Jul-2009	23-Jul-2009	FR	WAES0907USA02140	23-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NH4770		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Cyanosis, Grunting, Loss of consciousness, Pallor, Tremor

Symptom Text: Information was obtained on request by the company from the agency via a public case details form concerning a 13 year old female patient who on 08-JAN-2009 was vaccinated with a dose of GARDASIL (Lot: Batch: NH4770). On 16-JAN-2009, ten days post vaccination the patient was travelling in the back seat of a car and her mother heard grunting noise and noticed the child's head leaning to the side, her arms and legs then rose up and her body started to shake. The patient's lips were blue and skin color pale shade of grey, she was unconscious and this lasted 2-3 minutes. The patient's events caused or prolonged inpatient hospitalization (the patient was admitted to hospital). On 06-JAN-2009, the patient recovered from loss of consciousness, convulsion and pallor. The agency considered that loss of consciousness, convulsion and pallor were "possible" related to therapy with GARDASIL. The original reporting source was not provided. Additional Information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352132-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jul-2008	01-Aug-2008	8	22-Jul-2009	23-Jul-2009	FR	WAES0907USA02416	23-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1172U	2	Left arm	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthritis, Chest pain, Neuralgia, No reaction on previous exposure to drug, Nuclear magnetic resonance imaging abnormal, Oedema peripheral, Pleurisy, Serology positive, Tendonitis, X-ray abnormal

Symptom Text: Information has been received from a health professional concerning a 17 year old female who was vaccinated with the first dose of GARDASIL (Batch #NF56480/Lot #0251U) on 14-OCT-2007 and with the second dose (Batch #NF58550/Lot #0276U) on 15-JAN-2008). These were well tolerated. She was vaccinated with a third dose of GARDASIL (Batch #NH13130/Lot#1172U) injection route not reported, into the left upper arm on 24-JUL-2008. In August 2008 the patient experienced thoracic pain. Pleuritis and neuralgia were evoked as differential diagnosis. Pulmonary embolism and myocardial infarction were excluded. The patient recovered from thoracic pain after 4 weeks. Also in August 2008 the patient developed swelling of the left forefoot. In October 2008 diagnosis of enthesitis associated HLA B27 positive arthritis was established. Diagnosis was supported by serology, x-ray and MRI of the left foot (no detailed information provided). Unspecified treatment was carried out. The patient was not hospitalized. The patient had not recovered at the time of report. A persisting damage was reported. This was originally reported by a health professional. Other business numbers included E2009-05872. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352135-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Jul-2009	13-Jul-2009	5	22-Jul-2009	23-Jul-2009	FR	WAES0907USA02681	23-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1883U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, Syncope, Urinary incontinence

Symptom Text: Information has been received from a health professional concerning an 18 year old female who on 08-JUL-2009 was vaccinated with the third dose of GARDASIL (lot# 1883U, batch# NH50860) (dose, route not reported). 5 days later, on 13-JUL-2009, she was visiting the juvenile reception, by an unknown reason. At the reception, the girl experienced syncope and tonic-clonic cramps as well as urination. The woman was brought to the emergency and several tests (unspecified) and a data tomography was performed. Everything was normal. An Electroencephalogram (EEG) was planned as well as further investigations at the neurologist department. The patient received first and second dose of GARDASIL (dates and batch numbers not reported) without any adverse events. The outcome was not reported. Tonic-clonic cramps was considered to be an other important medical event. Other business partner numbers include E2009-05962. Case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Computed axial tomography, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352138-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
40.0	F	13-Mar-2009	20-Mar-2009	7	22-Jul-2009	23-Jul-2009	FR	WAES0907USA02418	23-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Dyspnoea, Fluid retention, Inappropriate schedule of drug administration, Oedema, Pitting oedema, Urticaria

Symptom Text: Information has been received from a health professional concerning a 40 year old female who on 13-MAR-2009 was vaccinated with the first dose of GARDASIL (IM, batch and site of administration not reported). On 20-MAR-2009 (7 day pv), she presented with urticaria treated with antihistamines, cortisone and ACTH. On 01-MAY-2009, urticaria reappeared with breathing difficulty, edema and diffuse arthralgia. The patient was hospitalized from 02-MAY-2009 to 06-MAY-2009 and received treatment with anti-histaminics. At the time of reporting, she presented with fluctuating fluid retention and fovea in lower limbs. The final outcome is not reported reported. This was originally by a health professional. Other business partner numbers included E2009-05910. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352141-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Apr-2009	29-Apr-2009	1	22-Jul-2009	23-Jul-2009	FR	WAES0907USA02415	23-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1400U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acid base balance, Drug administered at inappropriate site, Electrocardiogram, Laboratory test, Oxygen saturation, Syncope, Vaccination complication

Symptom Text: Information has been received from a paediatrician in hospital that concerning a 17 year old female who was vaccinated with a first dose of GARDASIL (Batch #NH38400/Lot#1400U) injection route not reported,into the thigh into the thigh on 28-APR-2009. The following morning at 08:00am the patient experienced syncope and unspecified complications after vaccination. The patient was hospitalised on an unspecified date. Diagnosis was confirmed by ECG,lab parameters,acid-base balance, monitoring of pulse, blood pressure and oxygen concentration. Duration of hospitalisation was not reported. However the patient recovered after 8 hours. This was originally reported by a health professional. Other business partner numbers included E2009-05870. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352147-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Oct-2008	08-Oct-2008	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA02122	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cardiac stress test, Cough, Drug exposure during pregnancy

Symptom Text: Initial information has been received from a nurse practitioner, for GARDASIL, a pregnancy Registry product, concerning a 17 year old female with asthma who on 08-Oct-2008 was vaccinated with 0.5ml first dose of GARDASIL (lot# 660393/0067X). Concomitant therapy included Albuterol. Subsequently the patient was pregnant. Pregnancy tests were preformed and unspecified medical attention was sought. On 08-Jan-2009 and 08-Apr-2009 the patient was vaccinated with a 0.5ml second and third doses of GARDASIL (lot# 660393/0067X) respectively. On 17-Mar-2009 the patient delivered a healthy baby boy in a hospital. No adverse effects were reported. Follow up information has been received from the nurse practitioner on 19-June-2009 concerning the patient. Concomitant therapy included Ibuprofen. The patient underwent stress testing at 8 months. Normal testing. Started prenatal care at 8 months (received no prenatal care prior to 35-36 weeks) On 17-Mar-2009 she delivered a normal, healthy male baby, weighing 7 pounds, at 40 weeks and 4 days from the LMP. The baby's length was 21 inches, head circumference was 14 inches. There was no congenital anomalies or other compilations. There were no complications during pregnancy or labor/delivery. Medication taken during pregnancy included cough medications (Nyquil), once, for cough, started in fall month of 2008. No further information is available.

Other Meds: Albuterol; Ibuprofen, 200 mg.

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP=6/10/2008) Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352148-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-May-2009	Unknown		17-Jul-2009	20-Aug-2009	VA	WAES0906USA02126	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diabetes mellitus

Symptom Text: Information has been received from a registered pharmacist concerning a 14 year old female with no medical history and no allergies who on 06-MAY-2009 was vaccinated with the 1st dose of GARDASIL, 0.5ml, IM (lot#661846/1312X). There was no concomitant medication. Subsequently the patient experienced unspecified diabetes symptoms. Her only abnormal lab was an increased in bilirubin. She had sought medical attention, and was seen. The patient's diabetes persisted at the time of report. Additional information has been requested.

Other Meds: None

Lab Data: serum direct bilirubin, increased in bilirubin

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352149-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	09-Jun-2009	10-Jun-2009	1	17-Jul-2009	20-Aug-2009	FL	WAES0906USA02135	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Blood pressure decreased, Chest pain, Diarrhoea, Influenza like illness, Malaise, Nausea, Pyrexia, Vomiting

Symptom Text: Information has been received from a physician concerning a 22 years old female with unknown medical history who on 09-JUN-2009 mid morning was vaccinated with the first dose of GARDASIL. On 10-JUN-2009 around 2:00 AM the patient started to feel nauseous, had vomited and had flu like symptoms. On 11-JUN-2009 around 5:00 AM the patient continued to feel sick and was also experiencing abdominal pain, diarrhea, chest pain, had a fever of 100.7F and her boyfriend who is an Emergency medical technician took her blood pressure which was low around the 70's. The patient had called physician for medical attention. It was unknown if the patient was going to receive the rest of the series. At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352150-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	02-Jun-2009	02-Jun-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA02136	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Musculoskeletal pain, Paraesthesia, Wrong technique in drug usage process

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female who on 25-MAR-2009 was vaccinated with the first dose of GARDASIL (intramuscular administration, lot#, site of administration not reported). On 02-JUN-2009 the patient received the second dose of GARDASIL (lot# 662229/1497X, intramuscular administration) which may had been administered in the bursa muscle. The patient experienced pain and tingling in the shoulder after receiving her second vaccination. The injection site was red and swollen and the pain radiated to the shoulder. On 08-JUN-2009 patient was seen in the office for pain. At the time of reporting the patient was not recovered. In follow up, a pharmacist called regarding the patient, requesting information on whether the dose should be repeated if it is administered in the bursa. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352151-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	CA	WAES0906USA02262	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL. Subsequently the patient experienced syncope. The patient sought medical attention in the physician's office. At the report time the outcome was unknown. This is one of several reports receiving from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352152-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	30-Mar-2007	13-Jul-2007	105	22-Jul-2009	27-Jul-2009	IL		29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0011U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Adverse drug reaction, Agitation, Anxiety, Convulsion, Dissociation, Dizziness, Dysarthria, Dysgeusia, Dyskinesia, Fatigue, Feeling abnormal, Frustration, Grunting, Headache, Hypoacusis, Insomnia, Irritability, Memory impairment, Muscle spasms, Oral contraception, Partial seizures, Speech disorder, Stress, Vision blurred, Visual impairment

Symptom Text: Seizures, Slurred speech, Dizziness, muffled hearing, blurred vision, involuntary joint movement, easily frustrated, muscle spasms, taste and memory disturbances, loss of sleep, extreme stress and anxiety related to symptoms and treatments. 7/23/09 Consultant records received DOS 7/31/07 to 7/13/09. Assessment: Partial seizure emanating from the left hemisphere. Patient "felt like something would happen" Then unable to speak appropriately, jumbled words, could not speak properly. Right arm made involuntary movements, felt like she was out of her body. Make loud noises. Hearing felt muffled. Felt on edge and not as sharp for 24 hours. Slightly mumbles, tired at times. Recurrent episode. Blotches in vision, headache. Agitated, irritability - Keppra. ICD-9 Code: 345.11, 780.39, 784.0 7/28/09 Medical records received DOS 5/30/07 to 1/29/09. Patient requests Gardasil vaccine. 1st dose of Gardasil given. Oral contraceptive changed from Desogen to Seasonique. Has had two seizures, on Keppra. 2nd, 3rd doses of Gardasil given. Denies any side effects from this medication (Gardasil).

Other Meds: N/A 7/28/09 Medical records received DOS 5/30/07 to 1/29/09. Oral contraceptives. Oral contraceptive changed from Desogen to Seasonique.

Lab Data: MRI, Multiple EEG, Multiplte Doctor Visits, all from having to traveling long distances. 7/23/09 Consultant records received DOS 7/31/07 to 7/13/09. LABS and DIAGNOSTICS: MRI - Normal. MRI angiogram normal. WBC / CBC normal. Comprehensive

History: N/A 7/28/09 Medical records received DOS 5/30/07 to 1/29/09 Caffeine.

Prex Illness: N/A

Prex Vax Illns: N/A~ ()~~0~Patient|N/A~ ()~~0~Sibling|N/A~ ()~~0~Sibling

Vaers Id: **352159-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	16-Jul-2009	16-Jul-2009	0	22-Jul-2009	30-Jul-2009	PA		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bite, Head injury, Loss of consciousness, Mouth injury

Symptom Text: Patient received a gardasil vaccine injection. Appeared fine, walked to front office to check out. Was speaking with the check-out person and without any warning fell to the floor. She was unconscious briefly. She hit her head on the floor and bit her lip. She was given smelling salts and ice was placed on her lip. She laid on the floor for about 20 minutes and was moved to an exam room where she was monitored for approximately 2 hours. She called her father and he picked her up to take her home.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 352169-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-Jul-2009	13-Jul-2009	0	23-Jul-2009	30-Jul-2009	CA		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Injection site pain, Presyncope, Vomiting

Symptom Text: Complained of feeling faint, lightheaded 2 minutes after receiving 1st dose of vaccine. She sat down in chair, nearly fainted, then threw up. She felt weak for remainder of day. The arm that received the vaccine was extremely sore for 5 days.

Other Meds: None

Lab Data:

History: None

Prex Illness: None-Very healthy, active 11 year old

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352170-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA02639	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Tooth loss

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female who on an unspecified date was vaccinated with third dose of GARDASIL (dose, route and lot number not reported). Subsequently the patient fainted and her two front teeth were knocked out. The patent eventually recovered on the same day and was able to "walk out of the office". The patient sought medical attention at the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352171-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	NY	WAES0906USA02641	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Nausea, Weight decreased

Symptom Text: Information has been received from a physician concerning a 19 year old female who about a year ago (in approximately 2008) was vaccinated with the third dose of GARDASIL (dose, route and lot number not reported). The physician reported that the patient's mother reported to him that soon after receiving the third dose of GARDASIL (in approximately 2008), the patient experienced nausea, weight loss, fatigue and joint pain. The physician reported that the patient was sent to see a rheumatologist and the results came back fine. The physician reported that the patient had recovered and was fine. The patient sought medical attention by contacting the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352172-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	04-May-2009	04-May-2009	0	17-Jul-2009	17-Aug-2009	CT	WAES0906USA02645	17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Diarrhoea, Dizziness, Nausea, Syncope, Vomiting

Symptom Text: Information has been received from a physician concerning his 24 year old daughter with no pertinent medical history reported and no known drug allergies, who "about six weeks ago" (on approximately 04-MAY-2009) was vaccinated with first dose of GARDASIL (dose, route and lot number not reported). Concomitant therapy included PROZAC during the week she had premenstrual syndrome. "The same day of vaccination" (on approximately 06-MAY-2009), the patient fainted and developed vomiting, diarrhea and dizziness. The patient recovered from fainted, nausea and vomiting, diarrhea and dizziness "about three days after vaccination" (on approximately 07-May-2009). No lab studies were performed. The patient sought unspecified medical attention. Fainted, nausea and vomiting, diarrhea and dizziness were considered to be disabling by the physician because the patient missed work. Additional information has been received from the physician who reported that he would not be supplying any more information about his daughter's event. Since his daughter had received the vaccine and experienced the event at come clinic in another city, he did not have the vaccine date, lot number or adverse event onset date. The healthcare professional contacted during the telephone follow up call could not supply the following information: date of vaccination, lot number or date of event. Additional information is not expected.

Other Meds: PROZAC

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352173-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Apr-2009	14-Apr-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA02647	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Upper respiratory tract congestion, Urticaria

Symptom Text: Information has been received from a physician's assistant concerning a 15 year old female who on 14-APR-2009 was vaccinated with second dose of GARDASIL (dose and route not reported, lot number 658563/1063U). The physician's assistant reported that after receiving the second dose, on the same day (14-APR-2009), the patient experienced congestion, hives and a rash on her face. The physician's assistant reported that the next day (15-APR-2009), "everything was cleared up and the patient was fine". The patient sought medical attention by calling the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352174-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-Feb-2009	20-Feb-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA02655	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gastrooesophageal reflux disease, Headache, Injection site pain, Sensation of foreign body

Symptom Text: Information has been received from a 22 year old female patient who on 20-FEB-2009 was vaccinated with the first 0.5 mL dose of GARDASIL. There was no concomitant medication. On 20-FEB-2009 (also reported as "two days after vaccination"), the patient experienced soreness at the injection site, headache and lump in her throat. Later the patient experienced acid reflux. The patient stated that she will not receive any further doses of GARDASIL. The patient sought unspecified medical attention. Two months later, on approximately 20-APR-2009, the patient recovered from soreness at the injection site, headache, lump in her throat and acid reflux. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 352175-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	11-Jun-2009	12-Jun-2009	1	17-Jul-2009	20-Aug-2009	--	WAES0906USA02657	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Nausea

Symptom Text: Information has been received from a physician concerning her daughter, a 26 year old female who on 11-JUN-2009 was vaccinated with the first dose of GARDASIL. On 12-JUN-2009, the patient experienced chills, headache and queasiness. The physician reported that the patient was still experiencing chills and headache and queasiness. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352176-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Jun-2009	15-Jun-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA02879	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Face injury, Fall, Immediate post-injection reaction, Loss of consciousness

Symptom Text: Information has been received from an office manager concerning a 17 year old female patient who on 15-JUN-2009 was vaccinated IM with a dose of GARDASIL (lot # not reported), 0.5 mL. It was reported that right after the patient received the GARDASIL she passed out, fell off the table and cut her face. She was brought to an emergency room but was unknown if she was admitted to the hospital. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352177-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-May-2009	12-May-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA02895	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHABB319AA		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C3029AA		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cyanosis, Dizziness, Feeling abnormal, Pallor, Syncope

Symptom Text: Information has been received from a registered nurse concerning a female patient who "3 weeks ago" on approximately 26-MAY-2009, was vaccinated with a dose of GARDASIL. Concomitant therapy included MENACTRA and other unspecified vaccines which were also given. On approximately 26-MAY-2009, after receiving the dose of GARDASIL the patient experienced syncope and turned blue. Oxygen was administered. The patient sought medical attention. The patient recovered within 20 minutes after the dose of GARDASIL was given. Follow-up information was received from a registered nurse concerning a 15 year old female patient. It was reported that on 12-MAY-2009, the patient received the first dose of GARDASIL (LOT # 661703/0651X). On 12-MAY-2009 the patient concomitantly received Tdap (manufacturer unknown) (LOT # C3029AA) and Hep A (manufacturer unknown) (LOT # AHABB319AA). It was reported that the patient did not receive concomitantly MENACTRA. After the patient had received GARDASIL, the patient became pale and light-headed. The patient never completely fainted. The patient's lips turned blue and the patient required oxygen for about 10 minutes. It took the patient "a long time before she felt normal". It was reported that the patient had eaten lunch before going to the physician's office. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352178-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Apr-2009	01-Apr-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA02901	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Tonic clonic movements

Symptom Text: Information has been received from a pharmacist concerning a female with unspecified drug reactions/allergies and medical history, who "a couple months ago" (approximately April 2009), was vaccinated with GARDASIL (dose, route and lot number unspecified). The pharmacist stated "A patient developed tonic-clonic movements directly after being given a dose of GARDASIL". At the time of this report the outcome of the patient was recovered (date unspecified). The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352179-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	20-May-2009	21-May-2009	1	17-Jul-2009	20-Aug-2009	--	WAES0906USA02915	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Injection site pain, Myalgia, Nausea, Vomiting

Symptom Text: Information has been received concerning a 23 year old female with latex allergy and no pertinent medical history who on 03-DEC-2008 was vaccinated IM with the first 0.5mL dose of GARDASIL (lot # 66012/0229X). On 04-FEB-2009 was vaccinated IM with the second 0.5 mL dose of GARDASIL (lot # 660612/0229X), and on 20-MAY-2009 was vaccinated IM with the third 0.5 mL dose of GARDASIL (lot # 661766/0652X). On 21-MAY-2009, the patient developed nausea, muscle arm soreness near the injection site, a temperature of 102 degrees F and 2 episodes of vomiting. The patient recovered on 22-MAY-2009. Additional information has been requested.

Other Meds: SEASONIQUE

Lab Data: body temp, 5/21/09, 102 degrees

History:

Prex Illness: Latex allergy

Prex Vax Illns:

Vaers Id: **352180-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2009	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA02926	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a pharmacist concerning a female who in June 2009, was vaccinated with a dose of GARDASIL (lot number, route and site of vaccination not reported). It was reported that the patient developed syncope immediately after a dose of GARDASIL. The patient sought an unspecified medical attention. At the time of reporting the patient's outcome was unknown additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352181-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Jun-2009	13-Jun-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA02932	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HEP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Heart rate, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female with no pertinent medical history who on 13-JUN-2009 was vaccinated with the first dose of GARDASIL. Lot number was not available. Concomitant therapy included (ADACEL) and hepatitis B virus vaccine (Unspecified). On 13-JUN-2009, the patient fainted after receiving her first dose of GARDASIL. The patient received all vaccines at the same time. The patient sought unspecified medical attention. Patient's heart rate was checked but no results were provided. On 13-JUN-2009, the patient recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 352182-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	27-Mar-2009	28-Mar-2009	1	17-Jul-2009	20-Aug-2009	--	WAES0906USA02937	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	659655/0940X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Migraine, Rash

Symptom Text: Information has been received from a certified medical assistant concerning a 26 year old female patient with penicillin, amoxicillin allergy and (PERCOCET) allergy who on 27-MAR-2009 was vaccinated with a dose of GARDASIL (lot# 659655/0940X). On 28-MAR-2009 the patient experienced a rash on both her arms lasting about 24 hours after vaccination with GARDASIL. She also experienced dizziness and migraines that lasted for a few weeks after vaccination. The patient sought medical attention via telephone call. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **352183-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	11-Jun-2009	12-Jun-2009	1	17-Jul-2009	20-Aug-2009	--	WAES0906USA02949	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pregnancy test, Smear cervix

Symptom Text: Information has been received from a 24 year old female with no pertinent medical history and no drug reactions/allergies who on 11-June-2009 was vaccinated with the first dose of GARDAISL. No concomitant therapies were included. The patient reported that she has nausea since 12-June-2008. The patient sought medical attention. A pap smear and a pregnancy test were done (resulted not provided). At the time of the reporting, the patient had not recovered. On follow-up information that patient wanted to know how long the nausea lasted in the clinical studio. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352195-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Jun-2009	12-Jun-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA02300	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Syncope

Symptom Text: Information has been received from a health professional concerning a 11 year old female patient who on 23-APR-2008 was vaccinated IM with the first dose of GARDASIL. On approximately 12-JUN-2009, 14 months after the first dose, the patient was vaccinated IM with the second dose of GARDASIL (lot# 661766/0652X). After received her second dose of GARDASIL, the patient experienced faint. The patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352197-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Jul-2009	21-Jul-2009	0	22-Jul-2009	30-Jul-2009	FL		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0187Y		Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	UF457CA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2868AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: Headache, dizziness AP 89 reg R-20 BP 104/64. Rested flat recovered after 15 minutes.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **352198-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	22-May-2009	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA02302	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female with no drug reactions or allergies who on 22-May-2009 was vaccinated with the second dose of GARDASIL. Concomitant therapy included ZYRTEC, DETROL, FLONASE and hormonal contraceptives (Unspecified). Subsequently on an unspecified date the patient experienced a bald spot. The patient did not seek medical attention. At the time of this report, the patient had not recovered. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: ZYRTEC; FLONASE; Hormonal contraceptives; DETROL

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352200-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	MN	WAES0906USA02309	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning an "around 12 year old" female with unknown allergies and unknown medical history who on an unspecified date was vaccinated with a dose of GARDASIL (dose number, vaccination date not reported). Subsequently, on an unspecified date after vaccination the patient had a positive papsmear test. Unspecified medical attention was sought. At the time of report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352201-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2009	01-Jun-2009	0	17-Jul-2009	20-Aug-2009	CO	WAES0906USA02313	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who about a week and a half ago approximately June 2009, was vaccinated with a dose of GARDASIL, MENACTRA and another vaccine (name and manufacturer unspecified) the patient went out in the parking and fainted. The physician reported that the patient's mother called the paramedics and then the patent was taken inside the office was monitored and then was able to leave the physician's office. The patient had recovered on the same day she received vaccine. The physician did not mention what the paramedics did when the patient was in the office parking lot. No further information is available.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352203-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Aug-2008	01-Sep-2008	31	17-Jul-2009	20-Aug-2009	CA	WAES0906USA02318	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Biopsy, Muscle injury, Rash

Symptom Text: Information has been received from a physician and company representatives concerning a 14 year old female who in approximately August 2008, was vaccinated with the 3rd of GARDASIL. Lot number was not available. In September 2008, approximately 1 month after receiving the 3rd dose the patient subsequently developed a rash, and she also developed muscle damage. At the time of report she was getting unspecified tests including a biopsy in the hospital but it was unknown if she was admitted to the hospital. She was currently under observation. She had not recovered at the time of report. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352204-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA02962	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with her second dose of GARDASIL (site and route of administration not reported). About two weeks post vaccination the patient experienced swelling at the injection site. The patient's swelling at the injection site persisted. No problem with the initial dose. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352205-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA02991	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lyme disease

Symptom Text: Information has been sent from a consumer concerning her daughter who on unspecified date was vaccinated with the second dose of GARDASIL (lot number, route and site not reported). It was reported that the patient was only able to receive two out of the three GARDASIL vaccinations. After the second vaccine she was diagnosed with Lyme's disease and was told that it was not good idea to give her any type of vaccination with an immune type disease such as Lyme. Therapy with human papilomavirus vaccine was discontinued. At the time of reporting the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352206-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	CA	WAES0906USA02514	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has bee received from a physician concerning a female who was vaccinated with a dose of GARDASIL. Subsequently the patient was taken to an emergency room. The reason the patient was taken to the emergency room was unspecified. At the time the outcome was unknown. This is one of several reports receiving from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352207-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA03285	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with GARDASIL. Subsequently the patient went completely bald after getting GARDASIL. The patient's outcome was unknown. This is one of several report's received from the same source. Attempts are being made to verify the existence of an identifiable patient.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352208-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	CA	WAES0906USA03335	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first dose of GARDASIL. The patient developed rash on her back a few days after receiving GARDASIL. The patient sought medical attention at the office. The outcome of the event was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352209-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA02576	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstrual disorder, Metrorrhagia

Symptom Text: Information has been received from a 21 year old female with no medical history who about 2 months ago in approximately April 2009, was vaccinated with her 1st dose of GARDASIL. Concomitant medication included hormonal contraceptives (unspecified). There were no labs and diagnostic tests performed. Subsequently the patient was spotting and her menstrual cycle was changing after getting GARDASIL. The patient hadn't sought medical attention. At the time of report the patient hadn't recovered. No further information is available.

Other Meds: Hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 352210-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Aug-2007	04-Aug-2007	1	17-Jul-2009	20-Aug-2009	VA	WAES0906USA02623	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pyrexia

Symptom Text: Information has been received from a licensed practical nurse concerning a 13 year old female who on 03-AUG-2007 was vaccinated with a dose of GARDASIL (lot # 653735/0688F). On 04-AUG-2007 the patient developed nausea and fever. The patient sought unspecified medical attention. The patient recovered from nausea and fever on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352211-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Jun-2009	14-Jun-2009	1	17-Jul-2009	20-Aug-2009	--	WAES0906USA03361	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Urticaria

Symptom Text: Information has been received from a consumer concerning a 15 year old female who on 13-JUN-2009 was vaccinated with the first dose of GARDASIL 0.5mL into the left arm. On 14-JUN-2009, the patient experienced pain, swelling and soreness at the injection site after getting the first dose of GARDASIL. Currently the patient developed hives on her left arm where the shot was given. At the time of the report the patient had not recovered. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352212-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	AZ	WAES0906USA03372	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on a unspecified date was vaccinated with a dose of GARDASIL (lot not reported) (the reporter was unsure of which dose this was in the series) and then the patient fainted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352213-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	16-Jun-2009	16-Jun-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA03400	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Presyncope

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female with a history of vasovagal responses, but not as a reaction to medications or vaccines who on 16-JUN-2009 was vaccinated with a 0.5 mL first dose of GARDASIL, intramuscularly. The patient had a vasovagal response after getting GARDASIL and she passed out cold. No laboratories studies performed. The patient sought unspecified medical attention. The patient recovered on 15-JUN-2009 after stopping therapy. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Vasovagal reaction

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352214-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Jul-2009	21-Aug-2009	MD	WAES0906USA03421	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Musculoskeletal stiffness

Symptom Text: Information has been received from a nurse concerning a female patient who on unspecified date was vaccinated with the first dose of GARDASIL vaccine (Lot nor reported). Subsequently the patient experienced headache and stiffness. The patient called her physician. The nurse reported that the patient was not going to finish the series of GARDASIL vaccine. At the time of report the outcome of the patient was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352215-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	IL	WAES0906USA03422	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Information has been received from the mother of the patient concerning a 14 year old female who on an unspecified day in February 2007 was vaccinated with the first dose, on an unspecified date the patient received her second dose and approximately in August 2007 third dose of GARDASIL (routes and lot numbers unspecified). Concomitant vaccine therapy included a dose of MENACTRA (dose, route and lot number not reported). The parent reported "the patient began experiencing chronic nausea 2 months after receiving her third dose of GARDASIL (October 2007). The patient went to the emergency room but was not admitted to the hospital (date unspecified). The patient started taking unspecified medication for chronic nausea. At the time of the report the outcome of the patient was recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352216-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	CA	WAES0906USA03424	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on an unknown date was vaccinated with the second dose of GARDASIL. It was reported that after getting the second dose of GARDASIL the patient fainted. It was reported that there was no information about the first dose of GARDASIL. The patient sought unspecified medical attention. On an unknown date, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352217-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Jun-2009	17-Jun-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA03428	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female patient with a broken toe who on 17-JUN-2009 was vaccinated IM with the first 0.5 mL dose of GARDASIL. On 17-JUN-2009 the patient fainted after receiving GARDASIL. The patient sought unspecified medical attention. A couple of minutes later the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Fractured toe

Prex Vax Illns:

Vaers Id: **352218-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Jun-2009	17-Jun-2009	0	17-Jul-2009	20-Aug-2009	NY	WAES0906USA03431	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Loss of consciousness, Musculoskeletal stiffness

Symptom Text: Information has been received from a nurse concerning a 17 year old female patient who "has a history of passing out, even if you just draw blood". On 17-JUN-2009 the patient was vaccinated with a first dose of GARDASIL (lot # not reported) 0.5ml, intramuscularly. After got the vaccine on 17-JUN-2009 "the patient passed out and got stiff". On 17-JUN-2009 the patient recovered. The patient sought unspecified medical attention. There were no laboratories diagnostics studies performed. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Passed out

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352219-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	VA	WAES0906USA03718	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection, Smear cervix

Symptom Text: Information has been received from a physician concerning a female with unknown medical history and unknown drug allergies who received all three doses of GARDASIL. Subsequently the patient presented with a high risk HPV. A PAP test was performed. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352220-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	16-Jun-2009	16-Jun-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA03719	03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Blood pressure increased, Blood test, Burning sensation, Dysgeusia, Pain, Paraesthesia

Symptom Text: Information has been received from a registered nurse concerning a 22 years old female with unknown medical history and unknown drug allergies who on 16-JUN-2009 was vaccinated with the first dose of GARDASIL at 4:00pm. Concomitant therapy included MUCINEX. "Starting at 10:30pm the patient started having episodes of weakness, burning, tingling pain and a metallic taste from her tongue to her toes." "She had these episodes 15-20 times before going to the hospital." At 12:23am on 17-JUN-2009 the patient went to the ER Room but was not admitted. She underwent unspecified blood work (results not reported). She was released at 3:45am that same day. When the patient got vaccinated her blood pressure was 125/72. At the hospital it was 156/94. The patient had recovered on 17-JUN-2009. Additional information has been requested.

Other Meds: MUCINEX

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352221-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	CA	WAES0906USA03736	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Genital herpes, Papilloma viral infection

Symptom Text: Information has been received from a physician assistant concerning a female patient who on unspecified dates was vaccinated with all three 0.5 ml doses of GARDASIL. At the time of vaccination the patient was not yet sexually active. Subsequently, after all 3 doses of GARDASIL the patient became sexually active and developed genital herpes. Unspecified medical attention was sought. It was noted that after the treatment the patient had two Papanicolaou (PAP) tests done. The first test came back atypical squamous cells of undetermined significance (ASCUS) and the second test came back high risk human papilloma viral (HPV). At the time of the report, the patient's status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, ASCUS; Pap test, high risk HPV (the second PAP test)

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352228-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Jun-2009	14-Jun-2009	6	23-Jul-2009	24-Jul-2009	FR	WAES0907USA00599	24-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1400U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Muscle tightness, Nausea, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a pediatrician via foreign agency concerning a 12-year-old female patient with a medical history of a tick bite on 04-APR-2009 who was vaccinated with a second dose of GARDASIL (lot-no. 1400U; Batch NH38400) IM into the upper arm on 08-JUN-2009. Some days p.v. the patient experienced the same but aggravated symptoms as after Dose 1. She was hospitalized for two days. Several investigations including EEG (electroencephalogram) and routine laboratory were carried out and showed no pathological findings. Borrelia serology was performed by the reporter on an unknown date. No pathological findings were established. At the time of reporting the patient had not recovered. The parents considered the event as related to the vaccine. Some days after first vaccination with GARDASIL on 06-APR-2009 the patient experienced headache, dizziness, nausea and fatigue. She recovered on an unknown date (info added 03-JUL-2009). Additional information received on 26-JUN-2009. The preliminary hospital report dated 21-JUN-2009 was provided. Lot number for Dose 2 GARDASIL was NH 38400. The patient was hospitalized from 18-JUN-2009 until 21-JUN-2009. On 14-JUN-2009 the patient experienced nausea and vomiting. Since 15-JUN-2009, mainly in the evenings, she complained of persistent headache. Under treatment with IBUPROFEN (Nurofen liquid) only slight improvement. But tendentially headache was improving at the time of admission. Upon admission general and neurological examination was without pathological findings. EEG (electroencephalogram) on 19-JUN-2009 showed no pathologies. In the course of the in-patient stay headache reoccurred again and again up to a value of 4 on a scale to 6. Medication with METAMIZOLE liquid was given. Thereunder amelioration of headache. A presentation at the ophthalmologist was recommended. On 21-JUN-2009 the patient was discharged in a good general condition. Upon reporting form dated 26-JUN-2009 the patient had not recovered at the time of reporting. Dose 1 GARDASIL, lot-no. 1

Other Meds: Unknown

Lab Data: Electroencephalography, 19Jun09, no pathological findings; Diagnostic laboratory test, routine laboratory: normal; Diagnostic laboratory test, routine laboratory: no pathological findings; Ophthalmological exam, emmetropia, no patholog

History: Tick bite; Neck rigidity; Headache; Dizziness; Nausea; Fatigue

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352229-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	NY	WAES0906USA03745	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL. Subsequently the patient fainted after receiving the GARDASIL. The patient had recovered (date unspecified). The patient had sought the physician for medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352230-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	10-Nov-2008	Unknown		23-Jul-2009	24-Jul-2009	FR	WAES0907USA02109	24-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Vaginal haemorrhage

Symptom Text: Information was obtain from a regulatory agency via a public case details form concerning a 20 year old female who on 10-NOV-2008 was vaccinated with a GARDASIL (Lot#not reported). The patient had a positive home pregnancy test on 24-NOV-2008. Atrioventricular septal defect was found on fetal morphology scan. The patient had vaginal hemorrhage after receiving GARDASIL. Amniocentesis was to be performed. The event required a specialist consultation. At the time of report on 15-JUL-2009, the outcome of the patient was unknown. The agency considered that all the symptoms were possibly related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: fetal monitoring tests, fetal morphology scan:Atrioventricular Septal Defect

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **352231-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	02-Apr-2009	07-Jun-2009	66	17-Jul-2009	20-Aug-2009	FL	WAES0906USA03753	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a female patient who in September 2008 and November 2009 was vaccinated with the first and second dose of GARDASIL. On 02-APR-2009 the patient was vaccinated with the third dose of GARDASIL IM 0.5ml. "A week and a half ago" on approximately 07-JUN-2009 the patient developed "a rash on her arms and legs". "The patient's other doctor" said that it was due to GARDASIL. Unspecified medical attention had been sought. No further information is available.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352232-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA03754	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who was vaccinated with GARDASIL. Subsequently the patient fainted. The patient had sought the nurse practitioner for medical attention and recovered (date unspecified). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352233-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
32.0	F	16-Jun-2009	19-Jun-2009	3	17-Jul-2009	20-Aug-2009	MA	WAES0906USA03807	29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Rash pruritic

Symptom Text: Information has been received from a 32 year old female consumer with sulfa and shellfish allergies and a history of endometriosis who on 16-JUN-2009 was vaccinated with the first 0.5ml dose of GARDASIL. Concomitant therapy included NORTREL. On 19-JUN-2009, the patient developed a painful, itchy rash on her arms, legs, chest and abdomen. Medical attention was sought by a phone call. There were no lab studies performed. The patient reported that she was now taking BENADRYL and the rash was improving. Additional information has been requested.

Other Meds: NORTREL

Lab Data: None

History: Endometriosis

Prex Illness: Sulfonamide allergy; Shellfish allergy

Prex Vax Illns:

Vaers Id: **352234-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Jun-2009	18-Jun-2009	6	17-Jul-2009	20-Aug-2009	--	WAES0906USA03821	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Headache, Nausea, Pyrexia, Swelling

Symptom Text: Information has been received from a nurse concerning a 19 year old female with a history of a "severe reaction to an unspecified meningitis vaccine" and no pertinent medical history who on 12-JUN-2009 was vaccinated with the first dose of GARDASIL (IM, lot number 658271/0558X). There was no concomitant medication. The patient experienced a fever, swelling and nausea on 18-JUN-2009, several days after the vaccination. Unspecified medical attention was sought. No lab/diagnostic studies were performed. It was noted that the patient recovered 2 days after onset of symptoms, on 20-JUN-2009. Follow-up information received from the nurse on 22-JUN-2009. At that time the patient continued to experience headaches but her fever resolved on 19-JUN-2009. The patient was experiencing trouble breathing. The patient took two doses of BENADRYL and breathing improved. The patient will not administered her second and third dose of GARDASIL. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Anaphylactic reaction to vaccine

Prex Illness:

Prex Vax Illns:

Vaers Id: **352235-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	22-May-2009	26-May-2009	4	17-Jul-2009	20-Aug-2009	PA	WAES0906USA03965	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a certified nurse practitioner concerning a 22 year old female with overactive bladder and allergies and no illness at the time of vaccination , who on 20-Mar-2009 and 22-May-2009 was vaccinated into the left deltoid with first dose (lot number reported as 13124, not valid) and second dose (lot number reported as U5581, not valid) respectively of GARDASIL. Concomitant therapy included FLONASE, ZYRTEC, birth control pills and DETROL LA. Four days after vaccination on 26-May-2009, the patient had a bald spot on head, she denied change in any medications. It was reported that nothing else was different. Additional information has been requested.

Other Meds: ZYRTEC; FLONASE; hormonal contraceptives; DETROL LA

Lab Data: Unknown

History:

Prex Illness: Overactive bladder; Hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352236-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	NY	WAES0906USA04017	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL. Subsequently the patient fainted after receiving the GARDASIL. The patient had recovered (date unspecified). The patient sought the physician for medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352237-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	18-Jun-2009	19-Jun-2009	1	17-Jul-2009	20-Aug-2009	TX	WAES0906USA04076	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bronchitis, Dyspnoea, Pain, Pyrexia

Symptom Text: Information has been received from a nurse concerning a 25 year old with a history of asthma female who on 18-JUN-2009 was vaccinated intramuscularly with the first 0.5mL dose of GARDASIL (LOT# 661531/1311X). On 19-JUN-2009, after receiving the dose, the patient developed shortness of breath, achiness and a fever of 101 F degree. The patient was treated in an emergency room. She was diagnosed with possible asthma or bronchitis or a reaction to the GARDASIL vaccination and treated with prednisone and ZITHROMAX. On 22-JUN-2009, the nurse spoke with the patient, and was told the patient was still achy, but was feeling better. Additional information has been requested.

Other Meds: Unknown

Lab Data: Body temp, 06/18?/09, 101 F

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **352239-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA04091	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	PPV	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia, Pain

Symptom Text: Information has been received from a physician concerning a 13 year old female who at time of vaccination with unspecified sickness was vaccinated with a dose of GARDASIL (LOT# not reported, duration and dose not reported). Secondary suspect vaccination included PNEUMOVAX 23 (duration and dose not reported) and another unspecified vaccine. It was reported that the patient was "already sick" at the time of vaccination and went to the office for a check up and was administered the vaccinations. After receiving vaccinations, the patient experienced muscle achiness and soreness. At the time of the report it was reported that the patient was recovering. No further adverse event information provided at this time of report. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Sickness

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352241-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	01-Jan-2009		17-Jul-2009	20-Aug-2009	PA	WAES0906USA04097	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Inappropriate schedule of drug administration, Paraesthesia

Symptom Text: Information has been received from a pharmacy technician concerning a female with a history of premature who in January 2009, was inadvertently vaccinated with the fourth dose of GARDASIL (LOT# not reported). After vaccination, the patient experienced numbness and tingling sensations on her arm. The patient had one dose from the patient's Gynecologist and received two doses from the patient's pediatrician. The patient sought unspecified medical attention and the outcome was unknown. No further information is available at this time of report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Premature baby

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352242-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Jul-2007	15-Jun-2009	715	17-Jul-2009	20-Aug-2009	--	WAES0906USA04116	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive, Smear cervix abnormal

Symptom Text: Information has been received from a consumer concerning his 22-year-old daughter who was vaccinated with all three doses of GARDASIL (dose, route and lot number not reported) and the last dose was received in July 2007. There were no concomitant medications. Last week (on approximately 15-JUN-2009) the patient had a PAP test done and it came back positive for HPV (unspecified which type). The patient had sought unspecified medical attention. At the time of the report, the patient's status was not recovered. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352243-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2009	01-Apr-2009	0	17-Jul-2009	20-Aug-2009	MO	WAES0906USA04127	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a consumer concerning her 16-year-old daughter with no medical history nor drug reactions/allergies who was vaccinated with the last dose of GARDASIL in April 2009, the reporter was not sure when the first dose was given but stated that the doses of GARDASIL were given "on time". There were no concomitant medications. After receiving the third dose of GARDASIL the patient's hair has been "falling out in clumps". The patient had not sought medical attention. At the time of the report, the patient's status was not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352244-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Jun-2009	22-Jun-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA04136	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a consumer concerning her daughter who on 22-JUN-2009 was vaccinated with the first dose of GARDASIL. On 22-JUN-2009 the patient fainted shortly after she took her first GARDASIL. The patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352245-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-May-2009	27-May-2009	0	17-Jul-2009	20-Aug-2009	NJ	WAES0906USA04137	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning an 18 year old female with no pertinent medical history and no drug reactions or allergies who on 27-MAY-2009 was vaccinated IM with the first dose of GARDASIL (lot # not reported). She also received a dose of MENACTRA and her first dose of HAVRIX. On 27-MAY-2009 about 1/2 hour to 1 hour after the vaccination the patient developed hives. The patient was seen in the office on 01-JUN-2009 for intermittent hives for a week. No lab diagnostics studies were performed. The patient's outcome was unknown. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352246-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA04269	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Headache

Symptom Text: It was reported in an internet article, concerning a female who was vaccinated with GARDASIL (date, dose, route not reported). The author of the article reported that "one girl who said she has suffered a headache non stop for 3 weeks now and it is destroying her quality of life. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352250-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Jul-2009	15-Jul-2009	2	23-Jul-2009	30-Jul-2009	NH		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site pruritus, Urticaria

Symptom Text: Mom called said she wanted it documented that pt had a reaction after the GARDASIL site was sore also came out in hives underarm gave BENEDRYL ok now. Pt reports that about 2 days post GARDASIL #2. The site of the immunization became very itchy, no rash noted at the site. Itching continued with application of BENEDRYL cream. It did not affect her activity. Mom confirmed above, and states itching did subside with a dose of BENEDRYL at beside. Two days later she developed hives under the opposite arm. It disappeared with one dose of oral BENEDRYL. She experienced no other symptoms and has been fine since. Mom did note that itching was documented on the Vaccine Information Sheet. Mom wanted to inform us since the Vaccine Information Sheet did advise reporting of hives. VAERS form will be completed and mailed upon discussion and evaluation by Physician.

Other Meds:

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352251-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-Jul-2009	02-Jul-2009	0	23-Jul-2009	30-Jul-2009	MO		31-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0171U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: HPV #1 lot# 0171U, exp 6/29/09 was given to pt. on 7/2/09. This vaccine was expired by 3days. Since this was first immunization, and will receive #2 and #3, no additional immunization will be given.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **352252-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Jul-2009	15-Jul-2009	0	23-Jul-2009	30-Jul-2009	MO		31-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0171U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: Received HPV # 3 on 7/15/2009. This vaccine expired on 6/29/09. Parents contacted. Will receive on additional HPV vaccine in 4 hrs to insure efficacy.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352255-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Jul-2009	15-Jul-2009	10	23-Jul-2009	30-Jul-2009	MO		31-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0171U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: Received HPV #3 on 7/15/09. This vaccine expired on 6/29/09. Parents contacted. Pt will receive an additional HPV vaccine in 4 months to insure efficiency.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352256-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jul-2009	21-Jul-2009	0	23-Jul-2009	30-Jul-2009	MO		31-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0171U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: Received HPV #2 7/21/09. This vaccine expired on 6/29/09. Parents contacted. Pt will receive an additional HPV vaccine 4 months after she receives her HPV# 3 to insure efficiency.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352260-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	17-Jul-2009	17-Jul-2009	0	23-Jul-2009	30-Jul-2009	NY		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Hypotension, Pallor

Symptom Text: Pt fell to floor post GARDASIL vaccine #2, 10 minutes post vaccine. Alert, responsive, pale. BP 70/50 - 78/60 - 86/60 - 92/70 - 98/70 - (Bumped L head.) WNL. Ice packs to head.

Other Meds: None

Lab Data: Monitored q5 minutes; discharged w/parent 10:45

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **352269-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Jul-2009	10-Jul-2009	0	23-Jul-2009	31-Jul-2009	TX		18-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	1584X		Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1130X		Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2877AA		Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B031AB		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pregnancy test positive, Rash

Symptom Text: Reported 7/23/09 - came to clinic to report pt got rash on arms, thigh after receiving vaccines. Pt took BENADRYL, used topical lotion for poison Ivy - 2 bottles on 7/10/09 till ?. Pt state pregnant did not tell nurse when nurse asked her before receiving vaccine - states she told her (nurse) she was not pregnant. Pt. states her preg test done with midwife - confirmed by urine test. No medical evaluation for rash - mom will take today to doctor.

Other Meds: None

Lab Data:

History: Sinus allergies - non specific 7/25/09; pregnant EDC 1/6/09 3 1/2 mo.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **352271-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Apr-2009	06-Jun-2009	63	17-Jul-2009	20-Aug-2009	--	WAES0906USA04379	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ear infection

Symptom Text: Information has been received from a consumer concerning her daughter, a 15 year old female who on 04-APR-2009 was vaccinated with the first dose of GARDASIL. The mother's patient stated that her daughter was suppose to receive the second dose of GARDASIL on 06-JUN-2009, because she had an ear infection. The outcome of the event was unknown. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352272-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Jun-2009	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA04389	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Information has been received from a registered pharmacist concerning a 17 year old female patient who on an unspecified date had been vaccinated with MENACTRA, prior to the first dose of GARDASIL (lot # not reported), IM route, that was administered on 17-JUN-2008. On an unspecified date, the patient returned to the office for her second dose of GARDASIL but was inadvertently given MENACTRA instead. The pharmacist mentioned that the lot number that was documented in her records correlated with MENACTRA. It began with an "M". The pharmacist was aware that the GARDASIL lot numbers are 4 numbers followed by an alpha and this was not how the dose was documented. On 30-DEC-2008, the patient returned to the office and received a third vaccination that was GARDASIL (lot # not reported), IM route. The pharmacist mentioned that the lot number patterns for the first and the third doses match the GARDASIL standard. No adverse effects were reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352273-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	23-Jun-2009	23-Jun-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA04393	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female with penicillin allergy and sulfonamide allergy and a history of fainting after getting her ears pierced who on 23-JUN-2009 was vaccinated IM with the first 0.5 mL dose of GARDASIL (lot # 658271/0558X). There was no concomitant medication. The patient felt light-headed a few minutes after receiving her first dose of GARDASIL. The patient rested and was monitored in the office. She subsequently recovered fully. Additional information is not expected.

Other Meds: None

Lab Data: None

History: Syncope

Prex Illness: Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: 352274-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	27-Oct-2008		17-Jul-2009	20-Aug-2009	--	WAES0906USA04724	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	5	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Colposcopy, Inappropriate schedule of drug administration, Smear cervix abnormal

Symptom Text: Information has been received from a health professional concerning an 18 year old female with prophylaxis who on 15-NOV-2006 was vaccinated with the first dose of GARDASIL (lot # 653978/0955F) 0.5 mL, I.M. route, on 17-JAN-2007 was vaccinated with the second dose of GARDASIL (lot # 655617/1447F) 0.5 mL, I.M. route, on 23-MAY-2007 was vaccinated with the third dose of GARDASIL (lot # 657736/0389U) 0.5 mL, I.M. route. Concomitant therapy included DESOGEN. The patient received a second series of GARDASIL. On 27-OCT-2008, was vaccinated with the first dose of the second series of GARDASIL (lot # 660616/0570X) 0.5 mL, I.M. route and had a PAP test abnormal. On 20-NOV-2008, the patient had a colposcopy (results not reported). On 17-FEB-2009, was vaccinated with the second dose of the second series of GARDASIL (lot # 661531/1311X) 0.5 mL, I.M. route. On 15-JUN-2009, was vaccinated with the third dose of the second series of GARDASIL (lot #660616/0570X) 0.5 mL, I.M. route and had a PAP test abnormal. At the time of the report the outcome of the event was unknown. The patient sought unspecified medical attention.

Other Meds: DESOGEN

Lab Data: Pap test, 10/27/08, abnormal; Pap test, 06/15/09, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352275-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	TX	WAES0906USA04739	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a 13 year old female who on an unspecified date was vaccinated with second dose of GARDASIL (dose, route and lot number not reported). It was reported that "a few minutes after receiving the second dose", the patient experience a syncope. The patient recovered "within 30 minutes to 1 hour". The patient sought medical attention by contacting the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352276-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA04750	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister

Symptom Text: Information has been received from a certified nurse midwife concerning a female patient with sulfonamide allergy who on an unknown date was vaccinated with the first dose of GARDASIL. It was reported that after the patient received the GARDASIL, she developed water blisters on her finger tips. The patient called the office in order to seek medical attention. At the time of reporting the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352277-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-May-2009	16-Jun-2009	19	17-Jul-2009	20-Aug-2009	--	WAES0906USA04767	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Headache, Nausea, Vomiting

Symptom Text: Information has been received from a Registered Nurse concerning a 16 year old female patient who on 23-MAR-2009 was vaccinated with a first dose of GARDASIL (lot# 0702X). On 28-MAY-2009 she received second dose of GARDASIL (lot # not reported). On 16-JUN-2009 she began experiencing a headache, nausea, vomiting and diarrhea. The patient sought unspecified medical attention. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352278-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Jul-2009	17-Aug-2009	--	WAES0906USA04859	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a physician's assistant who reported that a patient came into the office and reported that a friend of hers, who was vaccinated with GARDASIL had an adverse event (not further specified, no details reported) and was hospitalized. At the time of reporting the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352279-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	KY	WAES0906USA04941	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Impaired healing, Skin lesion

Symptom Text: Information has been received from a consumer mother concerning her daughter with no pertinent medical history and no known drug allergies who in 2008 was vaccinated with the third dose of GARDASIL (lot# not provided). There was no concomitant medication. Mother stated that she noticed after her daughter's third dose of GARDASIL, her daughter's cuts would bubble up when healing. The scars were more like lesions a quarter inch thick raised off the skin. Patient sought unspecified medical attention. No lab/diagnostic studies performed. At the time of this report patient had not yet recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Jan-2009	Unknown		17-Jul-2009	20-Aug-2009	CA	WAES0906USA04949	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MMR	MERCK & CO. INC.	0182U		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1311X	2	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	0270X		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye pain, Intraocular pressure increased, Myodesopsia, Photophobia, Retinal disorder, Surgery, Visual impairment

Symptom Text: Information has been received from a license practical nurse concerning her 19 year old daughter with no pertinent medical history who on 20-JAN-2009 was vaccinated with the third dose of GARDASIL (lot# 661531/1311X). Other suspect vaccines received on that same date included: MMRII (lot# 656034/0182U), VARIVAX (Merck) (lot# 659845/0270X) and MENACTRA. Subsequently, on the same day the patient developed vision problems. Few days later she complained of pain in her right eye. She saw many "floaters" in her field of vision. Patient sought medical attention. She went to see an ophthalmologist and tested normal. Then she became sensitive to the outdoor and indoor lights. She saw a specialist and he determined that she had "inflamed retinal bilateral". She was given steroids into her eye but the pressure still increased. She then saw another doctor who determined that she had massive pressure in her right eye with "rainbow vision" and performed a surgery on her right eye on 23-JUN-2009 in an outpatient clinic. At the time of this report the patient was in post surgical treatments, recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **352281-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA04961	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on an unspecified date was vaccinated with GARDASIL (lot # not reported), 0.5 mL, IM administration. The nurse stated that the patient was feeling uncomfortable after getting the GARDASIL, and she came back to the physician's office. The patient laid down and she later felt fine. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352282-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jun-2009	24-Jun-2009	10	17-Jul-2009	20-Aug-2009	--	WAES0906USA04977	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 24-JUN-2009 was vaccinated intramuscularly with the 0.5 ml first dose of GARDASIL (lot no. not reported). There was no concomitant medication. The physician reported that on 24-JUN-2009 the patient was still on the examination table when she experienced syncope. The patient was laid down on the table and recovered in seconds. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **352283-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA04981	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has bee received from a consumer concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). Subsequently, the patient developed fever for a couple of days. It was not specified if the patient sought medical attention.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352284-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	VA	WAES0905USA04982	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site reaction

Symptom Text: Information has been received from a physician concerning a 17 year old female who on an unspecified date was vaccinated with a dose of GARDASIL. The physician reported that "a couple of months ago", the patient experienced injection site reaction. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352290-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Jul-2009	23-Jul-2009	1	23-Jul-2009	30-Jul-2009	IN		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2906AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52BO36BA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0058Y	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Injection site urticaria

Symptom Text: large, red welt at site of vaccine. Pain at site.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352311-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	MI	WAES0908USA04987	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Colposcopy, Human papilloma virus test positive

Symptom Text: Information has been received from a registered nurse concerning 3 female patient who were vaccinated with a 0.5 mL third dose of GARDASIL, intramuscularly. The patients tested positive for HPV later. The patients had a colposcopy. The patients sought unspecified medical attention. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352312-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA04995	11-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a licensed practical nurse concerning her daughter with no medical history of allergies, who in October 2008, was vaccinated with first and only dose of GARDASIL, intramuscularly. There was no concomitant medication. The patient had been experiencing hair loss after receiving the GARDASIL vaccine dose. The reporter even noted a bald spot on patients head. No laboratories studies performed. The patient sought unspecified medical attention. At the time of this report the patient had not recovered. Additional information has been requested. 11/9/2009 PCP records for 2 visits 9/2009. Patient with c/o's hair loss, fungus on toenails, sore on foot. Impression: onychomycosis

Other Meds: None

Lab Data: None Labs none

History: None PMH: none Allergies: NKDA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352313-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	22-Jun-2009	23-Jun-2009	1	17-Jul-2009	20-Aug-2009	--	WAES0906USA04998	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling, Face oedema, Lip swelling

Symptom Text: Information has been received from a Physician Assistant concerning a 9 years old female who on 22-JUN-2009 was vaccinated with the first 0.5mL dose of GARDASIL (lot# not provided). There was no concomitant medication. On 23-JUN-2009 the patient developed facial edema like eyes, face and lips were swollen after getting the first dose of GARDASIL. Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352315-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Nov-2007	09-Dec-2008	403	17-Jul-2009	18-Aug-2009	--	WAES0906USA05000	26-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthropod bite, Bipolar disorder, Blindness, Deafness, Depressed mood, Dermatitis contact, Dizziness, Epistaxis, Eye pain, Feeling hot, Headache, Hyperreflexia, Local reaction, Loss of consciousness, Mass, Migraine, Nausea, Oropharyngeal pain, Pain, Pharyngeal erythema, Phonophobia, Photophobia, Presyncope, Pruritus, Rash erythematous, Skin exfoliation, Swelling, Syncope, Tinea infection, Vision blurred, Visual impairment

Symptom Text: Information has been received from a nurse practitioner concerning her 15 year old daughter who was administered all three dose of GARDASIL, and third dose was given in "October/November 2008" timeframe. It was reported that from last two months, the patient was experiencing dizziness and felt like fainting. There was an ECG test and results came normal. At the time of reporting, the patient had not recovered. The patient sought unspecified medical attention. Additional information has been requested. 8/3/09 Cardiology consultant records received DOS 7/16/09 Assessment: Neurocardiogen instability/vasovagal syncope. Patient c/o episodes of lightheadedness followed by blackness of her vision. Denies true syncopal episodes. Denies any other symptoms referable to the cardiovascular system. ICD-9 Codes: Light-headedness - 780.4 Syncope and collapse - 780.2 8/6/09 PCP medical records DOS 12/9/08 to 6/8/09. Assessment: Blacking out - unknown etiology. Sore throat, lump on right side of neck. Felt warm. Throat red. Rash on stomach, erythematous and scaly - tinea. Nose bleeds, dizzy spells, blacked out, head and eyes throb. For 2-3 minutes cannot hear or see. Birth control implant. 'Bug bite' on knees and foot, itch, hurt, swelling - local reaction. Rash on abdomen, arm, leg - contact dermatitis. 8/14/09 Neuro consult rec'd dated 6/30/09. Pt presented with c/o 1 month hx of headaches rated 10/10 on pain scale. Sometimes associated with nausea, blurry vision, seeing spots, photo/sonophobia. Also c/o intermittent lightheadedness and near syncopal episodes x 1 yr. Also dx with Bipolar d/o around that time, currently depressed. PE (+) for brisk refelexes. assessment: Migraine variant. Bipolar D/O, symptomatic.

Other Meds: Unknown

Lab Data: electrocardiogram, normal LABS and DIAGNOSTICS: ECG - WNL. Thyroid Studies WNL. Throat culture (-). Skin culture (-). CBC - Hematocrit 36.9% (L) EOSIN 6% (H) BASO 2% (H). Urinalysis (-) Urine Drug Screen (-). CHEM Calcium 9.2 MG/DL (L)

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352317-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Jun-2009	23-Jun-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA05017	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Pruritus generalised, Rash

Symptom Text: Information has been received from a nurse practitioner student concerning a 12 year old female with allergy to ROCEPHIN and no past medical history who on 02-APR-2009 was vaccinated with the first dose of GARDASIL (lot# 659180/1758U). The patient received her second dose of GARDASIL on 23-JUN-2009. There was no concomitant medication. It was reported that after second vaccination, the patient developed a rash over her face and itching over her body. The patient was treated with BENADRYL and ZYRTEC. The patient sought medical attention as the nurse spoke to patient's mother. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 352318-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	19-Jun-2009	19-Jun-2009	0	17-Jul-2009	20-Aug-2009	--	WAES0906USA05019	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 23 year old female with no known pertinent medical history, who on 19-JUN-2009 was vaccinated with the first dose of GARDASIL. Lot No was not provided. The physician reported that on 19-JUN-2009, the patient developed upper body rash after getting the first dose of GARDASIL. On 23-JAN-2009, the patient recovered. No laboratories diagnostic studies were performed. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **352319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Jul-2007	Unknown		17-Jul-2009	20-Aug-2009	--	WAES0906USA05048	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse concerning a 19 year old female who received all 3 doses of GARDASIL (on 27-DEC-2006 was vaccinated with the first dose, on 05-MAR-2007 with the second dose and on 12-JUL-2007 with the third dose) and at an annual check up at obstetrician's office, she tested positive for an HPV infection. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352320-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Oct-2008	21-Oct-2008	0	17-Jul-2009	21-Aug-2009	OH	WAES0906USA05055	02-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gaze palsy, Loss of consciousness, Syncope

Symptom Text: Information has been received from a office assistant concerning a 14 year old female with unspecified drug reactions/allergies and medical history, who on unspecified date in August 2008 and on 21-Oct-2008 received first and second doses respectively of GARDASIL (lot number for the second dose: 661044/0548X, route not reported). There was unspecified concomitant medication. The office assistant reported the patient was given the first dose of the vaccine and 5 minutes later the patient "passed out" on an unspecified date in August 2008. Also the office assistant stated the second time, the patient was given the vaccine, syncopal episode was more severe and more "seizure like" and the "patient's eyes rolled back" (approximately 21-Oct-2008). On an unspecified date the patient was recovered from this, but was not given the third dose. The patient sought medical attention by consulted physician. Follow up information has been received from the office assistant who reported the patient with no known allergies with attention deficit / hyperactivity disorder and she took STRATTERA 26mg each morning. On 01-Aug-2008, the only vaccine was the first dose of GARDASIL and that was the only vaccine received that day. Five minutes after injection, the patient passed out at the reception desk and she did not need treatment and recovered quickly. On 21-Oct-2008, the only vaccine administered was the second dose of the GARDASIL vaccine and on that date the reaction was worse, with "eyes rolling back". The patient did not lose consciousness and the physician was able to speak with her during the event. The office assistant said the physician was able to speak with her during the event. The office assistant said the physician used the term "seizure like", but in fact the patient did not have a seizure. Again no treatment was necessary. No labs / diagnostic were performed. The patient did not need to go to the ER. And the patient will be not receiving the third dose. No further information is available.

Other Meds: STRATTERA

Lab Data: Unknown

History:

Prex Illness: Attention deficit / Hyperactivity disorder

Prex Vax Illns:

Vaers Id: **352321-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Feb-2009	01-Feb-2009	0	17-Jul-2009	21-Aug-2009	--	WAES0906USA05091	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Syncope

Symptom Text: Information has been received from a physician concerning a 22 year old female who "four months ago" in approximately February 2009, was vaccinated with the first dose of GARDASIL and two months after the first dose, "two months ago" in approximately, April 2008, the patient was vaccinated with the second dose of GARDASIL. The physicist stated that he gave the first dose of GARDASIL and twelve hours later the patient's boyfriend called the doctor and stated that the patient fainted and then could not walk. The doctor sent the patient to the emergency room. A full workup was done. The patient was fine. There was no problems. The patient was not on birth control pills and she was not pregnant. The patient is fine now. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, full work up including a blood work up: the patient was fine

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352322-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	11-May-2009	Unknown		17-Jul-2009	21-Aug-2009	TX	WAES0906USA05163	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister

Symptom Text: Information has been received from a nurse concerning a 21 year old female who on 11-MAY-2009 was vaccinated with the first dose of GARDASIL (LOT# 661952/1129X). Concomitant therapy included NUVARING and MACROBID. On an unspecified date, after vaccination, the patient experienced blisters in her fingers and toes. The patient sought medical attention and spoke with a nurse. The patient's outcome was not reported. No other information was provided at the time of report. Additional information has been requested.

Other Meds: NUVARING; MACROBID

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352323-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Jun-2009	23-Jun-2009	5	17-Jul-2009	21-Aug-2009	FL	WAES0906USA05171	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning an 11 year old female who on 18-JUN-2009 was vaccinated with the first dose of GARDASIL (lot# 661953/1130X, route and site of administration not reported). Concomitant therapy included MENACTRA. On 23-JUN-2009 the patient came back in the office and presented her skin. The patient was diagnosed of urticaria all over her trunk and her leg in the thigh area. At the time of reporting the patient's outcome was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352324-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	21-Aug-2009	--	WAES0906USA05329	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a nurse concerning a female who on an unspecified date was vaccinated intramuscularly with a 0.5mL dose of GARDASIL (LOT# not reported). On an unspecified date, after vaccination, the patients experienced "2 episodes of syncope and dizziness"> The patient was sought unspecified medical attention and no outcome was provided. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352325-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	21-Aug-2009	PA	WAES0906USA05189	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who was vaccinated IM, 0.5 ml, with a dose of GARDASIL and then fainted. The patient sought unspecified medical attention. There were no laboratory studies performed. The patient had recovered immediately afterwards. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352326-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	25-Jun-2009	25-Jun-2009	0	17-Jul-2009	21-Aug-2009	--	WAES0906USA05359	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Fatigue, Mental impairment

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female who on 25-JUN-2009 was vaccinated with the first dose of GARDASIL (lot# 662518/0087Y, 0.5ml, route and site of administration not reported). Concomitant therapy included (ZOLOFT), amphetamine (ADDERALL TABLETS), (XANAX), (AMBIEN), (CLEOCIN) and (NUVARING). The patient's relevant medical history and past drug history were unknown. On 25-JUN-2009 the patient reported feeling weak, tired and mentally slow. As of 25-JUN-2009 the patient was still feeling weak, tired and mentally slow. It was unknown if the patient would continue to take the GARDASIL vaccine. Additional information has been requested.

Other Meds: XANAX; ADDERALL TABLETS; CLEOCIN; NUVARING; ZOLOFT;AMBIEN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352327-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Apr-2009	01-May-2009	30	17-Jul-2009	21-Aug-2009	SC	WAES0906USA05192	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Colposcopy

Symptom Text: Information has been received from a nurse concerning a 22 year old female who in April 2009, was vaccinated with her first dose of GARDASIL injection. In May 2009, the patient went to have her yearly Pap test done and her pap came back to the office today on 25-JUN-2009 to have a "colposcopy" done, and those results were not yet available. The patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, 05/??/09, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352328-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Jun-2009	10-Jun-2009	0	17-Jul-2009	21-Aug-2009	TX	WAES0906USA05197	03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Syncope

Symptom Text: Information has been received from a medical assistant concerning a 15 years old female who on 10-JUN-2009 was vaccinated intramuscular administration in arm with the first dose of GARDASIL (661952/1129X). Concomitant therapy included (VARIVAX) and unspecified hepatitis A virus vaccine. On 10-JUN-2009 the patient fainted and experiencing jerking movements after receiving her first dose of GARDASIL. The patient had sought unspecified medical attention. At the time of the report, the patient had recovered on 10-JUN-2009. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352329-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Jun-2009	08-Jun-2009	0	17-Jul-2009	21-Aug-2009	MI	WAES0906USA05225	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Drug exposure during pregnancy, Injection site pain, Loss of consciousness

Symptom Text: Information has been received from an 18 year old female patient with a history of fainting but no drug reactions or allergies who on 08-JUN-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL (lot# 659054/0315Y). There was no concomitant medication. The patient reported that "after received the first dose of GARDASIL she passed out and her left arm was sore where she received the injection". A nurse reported that after the patient received her first dose of GARDASIL vaccine the patient became faint. The office told the patient to lie down and raise her feet; she was also given oxygen, some fluid and crackers. Then the patient found out by doing a home pregnancy test that she was 5 weeks pregnant. Therapy with GARDASIL was discontinued on 08-JUN-2009. It was reported that the patient sought unspecified medical attention. The patient recovered after about an hour from "became faint and passed out" on 08-JUN-2009 and left the office. The patient's outcome was unknown for vaccine exposure during pregnancy and left arm sore where vaccinated. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, positive

History: SYNCOPE

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352330-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-May-2009	26-May-2009	0	17-Jul-2009	21-Aug-2009	VA	WAES0906USA05369	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 14 year old female with a history of passing out from other shots (name manufacturer unknown) who approximately in May 2009 was vaccinated with GARDASIL. After getting the vaccination the patient fell over and passed out. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: PASSED out

Prex Illness:

Prex Vax Illns:

Vaers Id: **352331-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Jun-2009	20-Jun-2009	3	17-Jul-2009	21-Aug-2009	NY	WAES0906USA05392	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness, Nuclear magnetic resonance imaging, Tremor

Symptom Text: Information has been received from a physician concerning a 11 year old female patient with no pertinent medical history and no drug reactions or allergies who on 17-JUN-2009 was vaccinated with a first dose of GARDASIL (lot# 661952/1129X) intramuscularly into left arm. Concomitant therapy included (MENACTRA). On 20-JUN-2009 " 72 hours after the first dose" the patient developed neck stiffness and some tremors in the left arm. On unspecified date magnetic resonance imaging (MRI) was performed (results not reported). The patient sought medical attention was saw by the physician. Additional information has been requested.

Other Meds: MENACTRA

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **352332-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Jun-2009	22-Jun-2009	0	17-Jul-2009	21-Aug-2009	--	WAES0906USA05615	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Myalgia, Paraesthesia

Symptom Text: Information has been received from a Nurse Practitioner (N.P.) concerning a 16 year old female patient who "about one week ago" (on approximately 22-JUN-2009) was vaccinated with the second dose of GARDASIL. It was reported that since receiving the vaccine, "about one week ago" (on approximately 22-JUN-2009) the patient had noticed her left arm, the arm where the injection was administered, had been feeling strange and tingly. It was reported that that patient had been lifting and cleaning at the camp and had reported other muscle type pain. The vaccines was not reintroduced. The patient sought unspecified medical attention. The patient had not recovered at the time of the report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352333-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
45.0	F	01-Nov-2006	01-Nov-2006	0	17-Jul-2009	21-Aug-2009	MI	WAES0906USA05616	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 45 years old female with no medical history and drug allergy who in November 2006, was vaccinated with the first dose of GARDASIL (lot number 653735/0688F). There was no concomitant medication. Prior to vaccination, the patient had a HPV DNA test which resulted negative in July 2006. On 2-JAN-2007, the patient received the second dose of GARDASIL (lot number 655205/1426F). In May 2007, the patient received the third dose of GARDASIL (lot number 657621/0387U). Her positive HPV DNA test was conducted on 16-JUN-2009. Also, the reporter mentioned that the patient is gay. The patient had sought unspecified medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: cervix HPV DNA assay, 07/??/06, negative; cervix HPV DNA assay, 06/15/09, positive

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352334-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	29-Apr-2009	01-May-2009	2	17-Jul-2009	21-Aug-2009	--	WAES0906USA05627	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a registered nurse concerning a female who two months ago was vaccinated with the first dose of GARDASIL. A few days after the vaccination, the patient experienced numbness and tingling in the opposite hand that was lasted until the time of report. It was unclear if the patient had or will continue with the series. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352335-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Jun-2009	22-Jun-2009	0	17-Jul-2009	21-Aug-2009	IL	WAES0906USA05641	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Nausea

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female with no pertinent medical history or allergies who on 22-JUN-2009 was vaccinated with the first dose of GARDASIL (lot# 662518/0087Y, 0.5ml, intramuscular administration). On 22-JUN-2009 the patient experienced chills and nausea after vaccination. On 25-JUN-2009 the patient visited the office for the results of her tuberculin skin test done on 22-JUN-2009 and mentioned chills and nausea which resolved on their own. The patient was recovered on 25-JUN-2009. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352336-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	21-Aug-2009	CT	WAES0907USA00009	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL. Subsequently the patient fainted. The patient's outcome was unknown. This is one of several reported received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352337-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	09-Jun-2009	09-Jun-2009	0	17-Jul-2009	21-Aug-2009	KY	WAES0906USA05666	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Loss of consciousness, Paraesthesia

Symptom Text: Information has been received from a nurse concerning a 23 year old female who on 09-UN-2009 was vaccinated with the first dose of GARDASIL (661764/0650X). Concomitant therapy included (LODRANE). On 09-JUN-2009 the patient passed out after the first vaccination. The patient was alright to leave the office but was recommended to go up to the urgent care. Then the next day. 10-JUN-2009, the patient called the office stating that the urgent care would not see her because she did not received the vaccination there and also stated she was experiencing dizziness. Then on 15-JUN-2009 the patient called the office and stated she was experiencing dizziness, headache and tingling all over her body. The nurse reported that the patient had not called back stating she was still having any issues so they were not sure how she was doing at this point. At the report time the patient status was unknown. Additional information has been requested.

Other Meds: LODRANE

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **352338-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Jul-2007	05-Jul-2007	0	17-Jul-2009	21-Aug-2009	PA	WAES0907USA00012	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Vaccination complication

Symptom Text: Information has been received from a nurse concerning a 13 year old female with AMOXICILLIN allergy who on 05-JUL-2009 was vaccinated with the first "standard dose" IM of GARDASIL (lot #657621/0387U). There were no concomitant medications. The nurse reported that the patient had a "reaction" after receiving the GARDASIL. The patient mentioned that she did not "feel good" after vaccination. The outcome was reported as recovered (date not reported). The patient did not seek medical attention. Additional information information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: PENICILLIN allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352339-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	21-Aug-2009	--	WAES0907USA00019	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a Licensed Practical Nurse concerning a female patient who on an unspecified date was vaccinated with a first dose of GARDASIL (date, dose and lot number unspecified). The nurse reported that the friend of one of her parents was diagnosed with an abnormal pap smear "about the same time she received her first dose of GARDASIL". At the time of the report the outcome of the patient was unknown. The patient sought unspecified medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352340-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Jun-2009	29-Jun-2009	0	17-Jul-2009	21-Aug-2009	NY	WAES0907USA00034	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1131X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: Information has been received from a nurse concerning a 16 year old female patient who on 29-JUN-2009 was vaccinated with a dose of GARDASIL (Lot: 661954/1131X) intramuscularly in the upper deltoid. There was no concomitant medication. On 29-JUN-2009 after receiving GARDASIL the patient fainted and fell on the floor of the waiting room. The patient went to the emergency room but was not admitted to the hospital. A CT scan of the head was performed (results not reported). On the same day on 29-JUN-2009, the patient recovered. Additional information has been requested.

Other Meds: None

Lab Data: Computed axial, 06/29?/09, CT scan of the head

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352341-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Jun-2009	08-Jun-2009	0	17-Jul-2009	21-Aug-2009	CT	WAES0906USA05668	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Head injury, Skin laceration, Syncope

Symptom Text: Information has been received from a physician concerning a female patient in her mid teens with a fear of needles who on approximately 08-JUN-2009 was vaccinated with GARDASIL (dose, route and lot # not reported). The physician reported that after receiving GARDASIL the patient fainted and hit her head on the table which caused her to have a laceration on her forehead. The physician reported that the patient came back a week later (approximately 15-JUN-2009) to the office and "potentially had a concussion" because the patient was "a little bit confused". The patient sought medical attention through an office visit. The patient's outcome was unknown. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Fear of needles

Prex Vax Illns:

Vaers Id: **352342-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Jul-2009	21-Aug-2009	NY	WAES0907USA00043	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope, Tonic clonic movements

Symptom Text: Information has been received from a physician concerning a female patient who was reported to be "14-16" year old who on an unspecified date was vaccinated with the first dose of GARDASIL. It was reported that the patient developed syncope with tonic clonic movements after receiving her dose of GARDASIL. The reaction happened within minutes of receiving the vaccine, while the patient was in the office. The patient sought medical attention while at the physician's office. There were no laboratory diagnostic test performed. It was reported that on an unspecified date the patient recovered. Upon internal review tonic clonic movements was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		17-Jul-2009	21-Aug-2009	TX	WAES0906USA05674	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tachycardia

Symptom Text: Information has been received from a physician concerning a 20 year old female patient who on unspecified date was vaccinated with a second dose of GARDASIL (lot number, route and site not reported). There were no drug reactions, allergies and other medical history. In approximately 2008, after receiving the second dose of vaccine, the patient experienced tachycardia, which was transient. The physician reported that the patient did not finish the GARDASIL series. The physician reported that was discontinued in approximately June 2008. The patient did not seek medical attention. No lab diagnostics study was performed. On an unspecified date, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352344-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Sep-2008	01-Sep-2008	0	17-Jul-2009	21-Aug-2009	--	WAES0907USA00064	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pyrexia, Vomiting

Symptom Text: Information has been received from a nurse concerning a 16 year old female with no medical history or drugs allergies, who in September 2008, was vaccinated with a first dose of GARDASIL. The patient received a second dose of GARDASIL on an unspecified date. The patient experienced nausea, fever and vomiting 6-9 hours after both doses. No laboratories studies performed. The patient sought unspecified medical attention. At the time of this report the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352345-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	22-Jun-2009	28-Jun-2009	6	17-Jul-2009	21-Aug-2009	--	WAES0907USA00070	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Rash, Tachycardia, Wheezing

Symptom Text: Information has been received from a physician's assistant concerning a 23 year old female patient with hallucinations induced by steroids who on 22-APR-2009 was vaccinated IM with the first dose of GARDASIL and on 22-JUN-2009 received IM the second dose of GARDASIL (lot #662518/0087Y). There was no concomitant medication. On 28-JUN-2009, the patient developed rash on lower extremities and chest, wheezing, tachycardia and intermittent fever. The patient sought unspecified medical attention. The patient's final outcome was not reported. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Drug-induced hallucinosis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352346-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Jul-2009	21-Aug-2009	--	WAES0906USA05677	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Face injury, Fall

Symptom Text: Information has been received from a nurse concerning an approximately 14 to 15 year old female who was vaccinated with what the nurse thought was the second dose of GARDASIL on an unspecified date. The nurse reported that the patient slid off the table on the floor and apparently "hit her face up pretty bad after the vaccination". The patient had been seated when she was vaccinated and the patient went from a seated position right to the floor. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352347-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	Unknown	Unknown		17-Jul-2009	21-Aug-2009	--	WAES0906USA05702	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Wrong drug administered

Symptom Text: Information has been received from a physician concerning his 11 year old son with a history of numerous unspecified unimmunisations who was possibly accidentally vaccinated with a dose of GARDASIL, in 2009, the patient was going to get immunizations when he might have accidentally received an injection of GARDASIL. In 2009 immediately after receiving the injection, the patient stated that he had received the incorrect injection. When the physician checked with the clinic that he had received the correct unspecified injection, the records showed that he had received GARDASIL. The clinic insisted that there was a mix up in paperwork and he had not actually received GARDASIL. In 2009 after possibly receiving the GARDASIL, the patient experienced excruciating pain at the injection site and swelling at the injection site, further described as being the size of a baseball. It was unknown if there was any laboratory data. As of 26-JUN-2009, the patient continues to experience pain at the injection site at the injection site. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **352348-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	27-Jun-2008	27-Jun-2008	0	17-Jul-2009	21-Aug-2009	--	WAES0907USA00075	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Immediate post-injection reaction, Influenza like illness, Joint lock, Migraine, Nausea, Pain in extremity, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female with no pertinent medical history reported and no known drug allergies who on 27-JUN-2008 was vaccinated with first dose of GARDASIL (lot number 660393/0067X). Concomitant therapy included birth control (name unspecified). The nurse practitioner reported that on her annual exam of this year (2009) the office noticed that the patient the rest of the series of GARDASIL. The patient stated that was because of the experienced she had after receiving the first dose. The nurse practitioner reported that immediately after receiving the first dose on 27-JUN-2008, the patient experienced flu-like symptoms, shortness of breath, nausea, vomiting, and her arm was sore; her shoulder locked up and had a severe migraine. It was reported that the symptoms lasted for about two days. The nurse practitioner reported that the patient had now recovered. No lab tests were performed. The patient sought medical attention by calling the physician. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352349-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	Unknown		17-Jul-2009	21-Aug-2009	CA	WAES0907USA00097	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall

Symptom Text: Information has been received from a physician concerning a 24 year old female with no pertinent medical history reported and no known drug allergies who "over six months ago" was vaccinated intramuscularly with first 0.5mL dose of GARDASIL (lot number not reported). There was no concomitant medication. The physician reported that the patient "got a little light headed and fell back. When she asked the patient what happened, the patient said that she had not eaten all day". The patient recovered later that same day. Since, the patient had gotten her second and third 0.5mL doses of GARDASIL (lot number not reported) and did not have an adverse event with either shot. No lab studies were performed. The physician attributed this adverse event to her not having eaten all day. the patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **352350-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	21-Aug-2009	--	WAES0907USA00122	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaccination complication

Symptom Text: It was reported in an internet article, concerning a female who was vaccinated with GARDASIL vaccine (date, dose, route not reported). The author of the article reported that "one girl on the site above went to the hospital 3 times for the reaction she was suffering before they finally admitted that this was a GARDASIL vaccine reaction. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352351-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2009	21-Aug-2009	--	WAES0907USA00144	21-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL. The physician reported a case of syncope or fainting following the vaccination. The patient also had Hep A (manufacturer unknown) and Tdap that same day. The physician reported that the patient fainting 5 to 10 minutes after the injection. The patient did not need any medical care, or going the emergency room, and did not die. The patient fully recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352352-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Jul-2009	21-Aug-2009	VA	WAES0907USA00182	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with GARDASIL. After getting the vaccination the patient experienced nausea. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352353-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Jul-2009	17-Aug-2009	--	WAES0907USA00330	17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Adverse reaction

Symptom Text: It was reported from an article, published on 29-JUN-2009 that there were "hundreds" of life-threatening reactions said to be associated with GARDASIL. This is one of several reports received from the same source. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Feb-2008	28-Feb-2008	0	17-Jul-2009	21-Aug-2009	CA	WAES0907USA01092	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Vomiting

Symptom Text: Information has been received from a physician concerning a 13 year old female patient with no pertinent medical history who on 28-FEB-2008 was vaccinated with a second dose of GARDASIL (lot number, route and site not reported). There was no concomitant medication. On 28-FEB-2008, the patient developed a fever and vomited after receiving vaccine. The patient had sought unspecified medical attention. The patient refused to have her third dose. On an unknown date, the patient recovered from a fever and vomited. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 352357-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Jun-2009	19-Jun-2009	0	24-Jul-2009	27-Jul-2009	FR	WAES0907USA03267	27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Bed rest, Brain contusion, Circulatory collapse, Concussion, Fall, Head injury, No reaction on previous exposure to drug, Retrograde amnesia, Syncope

Symptom Text: Case received from a health authority on 17-JUL-2009 under HA reference no. PEI2009015386. It was reported that a 17 year old female patient who was previously vaccinated with an unspecified number of doses of GARDASIL which were well tolerated, she was vaccinated with a dose of GARDASIL (lot number, injection site not reported) IM on 19-JUN-2009. A discharge summary was provided. About three minutes post vaccination the patient experienced an circulatory collapse and fell on her head followed by a short syncope in the gynecologist's practice. The patient lost her memory for about one hour. She experienced retrograde amnesia. On the same day the patient was hospitalized for monitoring and clarification. Clinical examination showed a right parietal contusion and commotion cerebri. Under observation and treatment with (CLEXANE) and bed rest the patient recovered and was discharged in good condition on 21-JUN-2009. Case is closed. Other business partner numbers include E2009-06045.

Other Meds: Unknown

Lab Data: Physical examination, 19?Jun09, showed a right parietal contusion and commotio cerebri

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352358-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-May-2009	24-May-2009	17	24-Jul-2009	27-Jul-2009	FR	WAES0907USA03266	27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1882U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Demyelination, Lhermittes sign, Lumbar puncture, Nuclear magnetic resonance imaging brain abnormal, Paraesthesia

Symptom Text: Information has been received from a Health Authority (case n. 101290), through foreign agency (Local case n. IT302/09). A 17 year old female patient was vaccinated with the first dose of GARDASIL (Batch number NJ21670 and Lot number 1882U, IM, site of administration not reported expired on 31-DEC-2010) on 05-MAR-2009 and 07-MAY-2009, respectively. On 24-MAY-2009, she presented with paresthesia of hands, lower limbs and trunk in D4 and D5 and positive Lhermitte's sign. The patient was hospitalized. Brain MRI, multimodal evoked potentials, lumbar puncture were performed. Diagnosis of relapse of demyelinating disease was made. The diagnosis was made with isoelectric focusing (IEF). The patient received intravenous and oral methylprednisone. At the time of reporting, the patient improved and recovered completely from neurologic symptoms but a slight Lhermitte's sign persisted. The patient had history of periventricular and corpus callosum demyelination and retrobulbar optic neuritis that recovered after corticosteroid treatment. The final outcome is not reported. Case is closed. Other business partner numbers included: E2009-06078. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, Isoelectric focusing (IEF): relapse of demyelinating disease

History: Demyelination; Optic neuritis retrobulbar

Prex Illness:

Prex Vax Illns:

Vaers Id: **352359-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Dec-2008	01-Jan-2009	31	24-Jul-2009	27-Jul-2009	FR	WAES0907USA03262	27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Migraine

Symptom Text: This case is poorly documented. Information has been received from a pharmacist concerning his 16 year old daughter who was vaccinated with a third dose of GARDASIL (lot, number, injection route and site not reported), on an unspecified date in December 2008. About one month post vaccination, in approximately January 2009, the patient developed headache. The patient was hospitalized on an unknown date. Several investigations including an EEG showed no pathological findings. A tumour and an intracranial bleeding were ruled out (not otherwise specified). Two months prior to the reporting date, the patient was diagnosed with suspicion of migraine and was under treatment at the time of reporting (not otherwise specified). Other business partner numbers included: E2009-05954. Additional information has been requested.

Other Meds: Unknown

Lab Data: electroencephalography, No pathological findings. A tumour and an intracranial bleeding were ruled out (not otherwise specified).

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352360-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Jul-2009	27-Jul-2009	--	WAES0907USA03043	27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from consumers concerning their "teenager" daughter who started to receive GARDASIL series over a year ago. The patient experienced seizures 3 weeks later after she received the 3rd dose of GARDASIL (date, lot number not reported). At the report time the patient had recovered. Upon internal review, seizures was determined to be another important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352361-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	13-Jul-2009	14-Jul-2009	1	24-Jul-2009	27-Jul-2009	FR	WAES0907CAN00083	27-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Nausea

Symptom Text: Information has been received from a female who on approximately 13-JUL-2009 was vaccinated with the third dose of GARDASIL, lot # not available. On approximately 14-JUL-2009 the patient experienced numbness in her hand/still occasionally feels numbness in her arm and nauseous. Numbness in her hand/still occasionally feels numbness in her arm was determined to be an important medical event based on foreign Agency requirements. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352364-1 (S)** **Related reports:** 352364-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Jun-2009	27-Jun-2009	18	24-Jul-2009	29-Jul-2009	CA		11-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acinetobacter infection, Areflexia, Blood product transfusion, Dysphagia, Endotracheal intubation, Gastrointestinal tube insertion, Guillain-Barre syndrome, Hypoaesthesia, Intensive care, Lumbar puncture, Mechanical ventilation, Muscular weakness, Neuralgia, Paraesthesia, Paralysis flaccid, Plasmapheresis, Pneumonia, Pneumonia staphylococcal, Pyrexia, Respiratory failure, Sensory loss, Walking aid user

Symptom Text: Developed progressive lower extremity weakness/numbness requiring intubation 6/30 for respiratory failure. EMG/MRI consistent with GUILLAIN-BARRE Syndrome. Remains intubated in ICU with flaccid paralysis and paresthesias. 8/10/09 PCP medical records received DOS 5/26/09 to 6/9/09. Gardasil administered. 8/17/2009 Received hospital medical records of 6/28-7/30/2009. FINAL DX: Guillain-Barre syndrome; respiratory failure s/p extubation; ventilator assoc acinetobacter & staph aureus pneumonia Records reveal patient experienced acute onset of progressive ascending LE weakness, areflexia & paresthesia, difficulty swallowing. Admitted to PICU, LP done & intubated. Developed neuropathic pain, fever w/(+) resp c/s. Neuro, Pulm, ID consult done. Tx w/IVIG w/o improvement, tx w/plasmapheresis x 8, multiple IV antibiotics, tube feedings. Continued to worsen. Gradually improved, extubated to RA & diet advanced. Transferred to inpatient rehab on continued IV antibiotics. 10/16/09 ICD-9 Codes received: 781.2 Abnormality of gait, 357.0 Ac infectious polyneuritis, 518.81 Acute respiratory failure, 997.31 Ventilator assoc pneumonia, 041.85 Infection-gram neg nec, 041.11 MSSA, 599.0 Urin tract Infection NOS, 345.90 Epilepsy NOS-Not intract. ```Rehabilitation hospital records, discharge summary received 2/5/10 and 2/8/10. Service dates 7/30/09 to 8/31/09. Assessment: Guillain-Barre Syndrome. Patient presented with loss of sensation and paresthesias lower extremities. Weak but able to move extremities. Improvement in strength, Pneumonia cleared. Voice usual strength. Discharged using walker.

Other Meds: LAMICTAL

Lab Data: MRI/EMG: demyelinating process consistent with Guillain-Barre/axonal damage 8/17/09 Medical records received w/LABS: CSF: protein 276(H), glucose 71(H). MRI brain & c-spine WNL. MRI ls-spine abnormal & c/w GBS. EMG/NCS abnormal. Re

History: absence seizures. 8/10/09 PCP medical records received DOS 5/26/09 to 6/9/09. Fever, throat hurting. 8/17/09 Medical records received w/PMH: absence seizure disorder.

Prex Illness: Sore throat/fever

Prex Vax Illns:

Vaers Id: **352364-2 (S)** **Related reports:** 352364-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Jun-2009	26-Jun-2009	17	15-Sep-2009	21-Sep-2009	CA		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Left arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abasia, Asthenia, Back pain, Blood product transfusion, Chest X-ray, Dysphagia, Dyspnoea, Dysstasia, Eating disorder, Endotracheal intubation, Feeling abnormal, Gastrointestinal tube insertion, Guillain-Barre syndrome, Heart rate increased, Hypoaesthesia, Hypokinesia, Intensive care, Mobility decreased, Pain, Pain in extremity, Paralysis, Pneumonia, Posture abnormal

Symptom Text: Friday, June 26, 2009 morning - complained that her legs felt funny. Evening - complained her legs weren't working correctly and she couldn't run. Saturday, June 27, 2009 morning - unable to walk without assistance, fell if she tried to stand. Morning- taken to the local ER, sent home with crutches & a diagnosis of growing pains. Evening- unable to walk and cannot use arms. Evening - taken to ER an hour and 20 minutes from our home, preliminary diagnosis Guillain Barre Syndrome and was told she would be admitted to the hospital. Sunday, June 28, 2009 afternoon - admitted to Intermediate ICU from the ER. Evening - slowly things got worse, the numbness/paralysis continued progressing up her legs/arms, complained of incredible back and leg pain. First of 5 doses of IVIG began, one dose per day for 5 consecutive days. Monday, June 29, 2009 continual progression of paralysis throughout the day. Struggling to breathe. Oxygen thru a nasal canula used to help with breathing. Patient continued to be in pain. Placed on a feeding tube, unable to eat and swallow correctly. Tuesday, June 30, 2009 continued to struggle to breath. Still in continual pain. Very weak, neck was "baby like" and unable to support head. Very late transferred to the PICU for observation and placed on a Bi-Pap ventilator. Wednesday, July, 1, 2009 struggled with breathing, heart rate increasing throughout the day. Intubated between 11:30 and midnight. By this time paralysis was almost complete, no movement of legs and very little movement of arms, paralysis had obviously moved into the diaphragm causing the breathing problems. Patient was intubated for almost 4 weeks. During this time she had 2 bouts of pneumonia, numerous chest x-rays, respiratory treatments, MRI's, a PIC line was put in place, a central line was put in place for 8 plasmapherisis treatments, an EMG and SSEP confirming the diagnosis of Guillain Barre Syndrome. Patient also had had a rapid heart rate for some time. It isn't back down to normal. Patient is current

Other Meds: LAMOTRIGNE

Lab Data: Lumbar Puncture; EMG; MRI

History: Seizures

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352366-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Jul-2008	11-Jul-2008	0	24-Jul-2009	31-Jul-2009	MD		14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C2889AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Dyspnoea, Panic attack

Symptom Text: Had a panic attack (shortness of breath, confusion) 20 minutes after administration of meds. No hives on swelling noted.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352377-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Jun-2009	20-Jun-2009	2	24-Jul-2009	31-Jul-2009	MI	MI2009007	31-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB258AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hypophagia, Loss of consciousness, Mouth injury, Suture insertion

Symptom Text: On 6/20/09 per parent, client got out of bed at 9:00 Am, without eating or drinking went to use bathroom. Client felt dizzy (told this to Dad), then passed out "for a few seconds" Hit her mouth on bathroom counter. Went to ER for stitches and had EKG (results neg). On menstrual period.

Other Meds: None

Lab Data: EKG

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **352379-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jul-2009	23-Jul-2009	0	24-Jul-2009	31-Jul-2009	PA		24-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1275X	2	Left arm	Subcutaneously	
MMR	MERCK & CO. INC.	1726X	2	Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB33UDA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	00874	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction

Symptom Text: Patient got lightheaded immediately following vaccinations. Sat Pt down, used smelling salt, gave pt sips of ice tea, had pt sit an additional 20 minutes , released to care of father.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352388-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Jul-2009	22-Jul-2009	1	24-Jul-2009	31-Jul-2009	FL		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1715X	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0570X	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	UFY55CA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2844AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling

Symptom Text: Swelling and redness/induration (R) upper arm at site of inj measuring 7cmX7cm.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352389-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	23-Jul-2009	23-Jul-2009	0	24-Jul-2009	31-Jul-2009	MI		18-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3029AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	42813AA	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB296AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Patient fainted directly after administration of HPV. Mom and nurse slid her to floor where she regained consciousness. (This was 3rd of 4th shots given)

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352390-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Jul-2009	24-Jul-2009	0	24-Jul-2009	31-Jul-2009	FL		31-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Immediate post-injection reaction

Symptom Text: Patient tolerated the HPV vaccine injection well. However 5 minutes after the vaccine was given she fell to the floor she was awake and alert and aware of her surroundings. Stayed in office for 30 minutes with no tender complication.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **352397-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Jul-2009	21-Jul-2009	0	24-Jul-2009	30-Jul-2009	IL		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0261Y	1	Left arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB320AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0558X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2689AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3028BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling, Injection site warmth

Symptom Text: Injection site swollen to softball size, hard, red and warm to touch. Went to ER and was discharged to home with prescriptions for Crphalexin 500 mg TID and Methylprednisolone 21 day dose pack.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352398-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jul-2009	23-Jul-2009	0	24-Jul-2009	30-Jul-2009	MI		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	14460	3	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2842AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B0339AA	5	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Hyperhidrosis, Immediate post-injection reaction, Pallor

Symptom Text: Immediately after receiving Tdap, Menactra, and HPV at 3:15 pm patient reported feeling dizzy, weak. Pale, sweating, no loss of contiousness, pt. placed in supine position on floor with legs elevated. BP 98/68, p. 88, 3:20 pm reported feeling better, 98/64, p. 84, color improved and able to sit upright. 4 pm, released in care of brother, pt. advised no driving today, to ER increase symptoms. Verbalized understanding.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **352399-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
34.0	F	17-Jul-2009	19-Jul-2009	2	24-Jul-2009	30-Jul-2009	CA		30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site lymphadenopathy, Injection site pain, Lymphadenopathy

Symptom Text: Swollen glands around neck, breast and armpit area where injection was adminstered. The area was very tender.

Other Meds:

Lab Data:

History: No

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352403-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Jul-2009	23-Jul-2009	1	24-Jul-2009	30-Jul-2009	WI		31-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	095X1		Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3027AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2819AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1312X1		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site papule, Injection site warmth

Symptom Text: Varicella administered on 7/22/09. Noticed red/bumpy silver dollar sized @ site. 7/24/09 came to HD measured 6cm/8cm red/bumpy/warm.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 352421-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Jun-2008	22-Jun-2008	13	27-Jul-2009	30-Jul-2009	SC		09-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Allergy test positive, Antinuclear antibody negative, Arthralgia, Asthenia, Borrelia burgdorferi serology negative, Colonoscopy, Computerised tomogram, Condition aggravated, Constipation, Diarrhoea, Endoscopy, Epstein-Barr virus infection, Fatigue, Feeling abnormal, Food allergy, Food intolerance, Full blood count normal, Hypoaesthesia, Insomnia, Laboratory test normal, Myalgia, Nausea, Neuropathy peripheral, Nuclear magnetic resonance imaging, Oesophagogastroduodenoscopy, Pain, Paraesthesia, Phonophobia, Red blood cell sedimentation rate normal, Rheumatoid factor negative, Vomiting, Weight decreased, Wheat-free diet

Symptom Text: Nausea & vomiting, abdominal pain, joint pain, numbness & tingling in hands & feet, fatigue, weight loss. Unable to eat certain foods. Developed allergy to wheat. These symptoms started 1 to 2 weeks after 1st vaccine. Pt stated felt like "she was 80 yrs old." Started wheat free diet, visited doctor, lab tests for celiac disease negative, numerous lab tests (lyme titer, cbc, rheumatoid workup, ANA, Sed rate, lupus and all negative. 2 months after vaccine peripheral neuropathy, joint pain symptoms improved. Continues with abdominal pain, weakness, weight loss & difficulty with foods. Diarrhea begins and continues to present. Work up by GI specialist includes EGD, colonoscopy, CT's, MRI, GI series, video capsule endoscopy, numerous lab studies. Allergy testing showing allergy to wheat. Positive for fructose malabsorption. Wheat free & fructose free diet. Work up continues after 1 year to find source of abdominal pain and watery diarrhea. 7/30/09 PCP records received 7/11/08 to note written 7/28/09. Initially presented 7/11/08 request to be tested for celiac disease. Reports 2 yr hx of abdominal pain, recently improved on wheat-free diet. Returned 8/11/08 with c/o 2 months hx of "everything hurting"- joints and muscles, fatigue, decreased sleep, sensitive hearing. Labs all WNL except (+) EBV Ab IgG showing recent infection. 10/8/09 Hospital records, DC summary received, service dates 3/16/09 to 3/18/09. Assessment: Chronic complex of abdominal pain with diarrhea. Patient developed myalgias, asthenia, fatigue, arthralgias, nausea and vomiting - now resolved. Lost weight. Constipated. Patient now presents with abdominal pain and postprandial diarrhea. Abdomen - diffuse tenderness to palpation. ICD-9 Codes: 564.1 Irritable bowel syndrome, 787.91 Diarrhea.

Other Meds:

Lab Data: Small bowel biopsy with intraepithelial lymphocytes. Labs: EBV IgG (+). 10/8/09 Hospital records 3/16/09 to 3/18/09. LABS and DIAGNOSTICS: CT Scan Abdomen/Pelvis - Abnormal.

History: Pectus Excavatum PMH: abdominal pain. 10/8/09 Hospital records 3/16/09 to 3/18/09. Blastocystis hominis infection. Possible Joubert's Syndrome.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352455-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	21-Jul-2009	22-Jul-2009	1	27-Jul-2009	03-Aug-2009	CA		03-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2773BA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2730AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Syncope, Tremor

Symptom Text: Fainted briefly after - body was shaking - Immunization in this order: (1) MENACTRA - (2) ADACEL - (3) GARDASIL

Other Meds:

Lab Data: Referred to hospital EN bec. continued dizziness.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352458-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jul-2009	17-Jul-2009	1	27-Jul-2009	31-Jul-2009	PA		18-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0684Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0312Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site erythema, Injection site swelling, Injection site warmth, Lethargy, Paraesthesia

Symptom Text: Mother reports, 7/17/09 Pt. had redness, swelling, tingling of left arm approximately from elbow to slightly below shoulder, area was very hot. Pt. was lethargic and had a head ache. Most symptoms resolved by 7/19/2009 am. Pt still has pink around injection site as of date of report.

Other Meds:

Lab Data:

History: Food allergy - Citrus

Prex Illness:

Prex Vax Illns:

Vaers Id: 352469-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Dec-2008	13-Jan-2009	33	27-Jul-2009	28-Jul-2009	FR	WAES0907USA03265	28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1941U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Aphasia, Fatigue, Fine motor delay, Headache, Muscle twitching, No reaction on previous exposure to drug, Thirst, Tremor

Symptom Text: Information has been received from a Health Authority (ref. # DK-DKMA-20091722) concerning a 14 year old female patient with no concurrent disease who on 11-DEC-2008 was vaccinated with the second dose of GARDASIL (Lot # 1941U and Batch # NJ01850) intramuscularly (site of administration not reported). The patient received no concomitant vaccine or medicine. It was reported that on 13-JAN-2009, the patient experienced an episode with twitching flexor of upper and lower extremity, tremor, some expressive aphasia, fine motor delay, headache and subsequently tiredness and thirst. It was reported that the patient was admitted to the hospital (no further specified). MR scan of cerebrum, EKG and analysis of Hb, infection parameter, liver count, kidney numbers, and glutamic acid revealed no abnormalities. No investigational analysis were specified further. On 02-OCT-2008, the patient was vaccinated with the first dose of GARDASIL (Lot # 1941U and Batch # NJ01850) intramuscularly (site of administration not reported). No adverse reaction was reported. Other business partner numbers include: E2009-06102. No further information is available.

Other Meds: None

Lab Data: magnetic resonance imaging, no abnormalities; electrocardiogram, no abnormalities; diagnostic laboratory test, infection parameter; no abnormalities; diagnostic laboratory test, Liver count; no abnormalities; diagnostic laboratory test, Kid

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352470-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Jun-2009	15-Jun-2009	7	27-Jul-2009	28-Jul-2009	FR	WAES0907USA03268	28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U	0	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Influenza like illness, Paraesthesia, Pyrexia, Sensory loss, Visual field defect

Symptom Text: Information has been received from Foreign Health Authority (HA reference number: PEI2009015490), concerning 12-year-old female patient who was vaccinated with a first dose of GARDASIL (lot number: 1427U, batch number: NH17960, injection route not reported) into the left upper arm on 08-JUN-2009. On 15-JUN-2009 the patient experienced flu-like symptoms with fever for two to three days. On 17-JUN-2009 the patient developed visual field defect, sensory deficit reported as a "sock like" of the left upper arm and tingling of the left hand. On an unspecified date the patient was hospitalized. In cranial MRI (magnetic resonance imaging) was not indication of multiple sclerosis and acute disseminated encephalomyelitis. An ophthalmologist confirmed circular visual field defect on both sides but no other pathological findings. At the time of the reporting to HA (19-JUN-2009) the patient had not recovered. Other business partner numbers included E2009-06043. The reporter felt that the patient's experiences were important medical events. No further information has been received.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, ??Jun09, No indication of multiple sclerosis-see narrative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **352471-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Jul-2009	14-Jul-2009	1	27-Jul-2009	28-Jul-2009	FR	WAES0907USA03269	28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1695U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, No reaction on previous exposure to drug, Partial seizures

Symptom Text: Information has been received from a pediatrician concerning a 15 year old female with history of convulsion disorder who on 13-JUL-2009 was vaccinated with the second dose of GARDASIL (lot#1695U, batch # NH25730). Concomitant therapy included LAMICTAL. During the following night, when she slept overnight at a girl-friend, the patient experienced a focal seizure. She did not seek medical attention after the event. The reported pointed out that the patient was currently in a critical condition as the parents were separating. In the last two years, the patient had been free of seizures under treatment with LAMICTAL and had normal EEG controls. The first dose of GARDASIL was administered on an unspecified date, was well tolerated. Focal seizure was considered to be an other important medical event. Other business partner numbers included E2009-05979. The case was closed. No further information is available.

Other Meds: Lamictal

Lab Data: Electroencephalography, normal the last two years.

History: Convulsion disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: 352472-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Mar-2009	Unknown		27-Jul-2009	28-Jul-2009	CA	WAES0907USA03354	28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a 25 year old female patient with no pertinent medical history who in approximately March 2009, was vaccinated with a first dose of GARDASIL (lot number, route and site not reported). There was no concomitant medication. Subsequently the patient determined to be pregnant. The patient's menstrual period was not reported. The patient experienced a spontaneous miscarriage on an unspecified date. The patient had sought unspecified medical attention. At the time of report, the patient had recovered on an unspecified date. The physician felt that spontaneous miscarriage was not related to therapy with GARDASIL. Upon internal review, spontaneous miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **352473-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		27-Jul-2009	28-Jul-2009	--	WAES0907USA03373	28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Blood test, Cardiac monitoring, Myalgia, Paraesthesia, Syncope

Symptom Text: Information has been received from a consumer concerning her 19 or 20 year old niece with no known drug reactions/allergies and no pertinent medical history who over a year ago was vaccinated with the third dose of GARDASIL. There were no concomitant medications. The consumer reported that since receiving the third dose her niece had experienced ongoing occasional joint pain, muscle pain, tingling in her hands, and fainting spells ever since and was hospitalized. Labs diagnostic studies performed included checked heart and blood work (results not provided). At the time of reporting the patient had not recovered. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352474-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		27-Jul-2009	28-Jul-2009	CO	WAES0907USA03589	28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Information has been received from a registered nurse concerning a female patient who on an unknown date was vaccinated IM "either with the first or third 0.5 mL dose" of GARDASIL. The nurse reported that when she gave the patient GARDASIL, the patient started to pass out. The nurse gave the patient water and she seemed okay. Later the nurse noticed the patient looked like she was having seizure. It was reported that the patient's mother was trying to blow air into the patient's mouth, but it is unknown if she tried to it during or after the patient looked like she was having a seizure. The patient sought unspecified medical attention. The patient's final outcome was unknown. Upon internal review seizure was considered to be another important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352481-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
2.0	F	21-Jul-2009	21-Jul-2009	0	27-Jul-2009	03-Aug-2009	NC		13-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Dizziness, Fatigue, Heart rate increased, Nausea, Pain, Pain in extremity, Pyrexia, Rash, Vomiting

Symptom Text: Fever to 102 degrees F nausea, vomiting -> (severe) dizziness, rapid heartbeat, rash, aches/pain in legs, knees, ankles, weakness/ extreme fatigue. Onset about 6-7 hours after inoculation, treated with TYLENOL, MOTRIN, Dr. prescribed ZOFRAN for nausea. 6 PM through the night. Fever broke by 10 am following day

Other Meds:

Lab Data:

History: Asthmatic

Prex Illness: None

Prex Vax Illns:

Vaers Id: 352496-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Jul-2009	22-Jul-2009	0	27-Jul-2009	28-Jul-2009	--	WAES0907USA03631	28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Hyperventilation, Muscle rigidity, Syncope, Vomiting

Symptom Text: Information has been received from a Nurse Practitioner concerning a 17 year old female with a history of neuro- surgery in 2001 for malformation and laparoscopic surgery on left ovary for cyst who on 22-JUL-2009 was vaccinated with a first dose of GARDASIL (lot # not reported) 0.5ml, intramuscularly. There was no concomitant medication. On 22-JUL-2009 after vaccination the patient experienced syncope. Afterwards for 1-2 minutes, the patient experienced what appeared to be a seizure. The symptoms include tightening and straightening of the body with heavy breathing. An ammonia capsule was used. Also, it was mentioned that the patient vomited at home. In the afternoon, the patient was oriented and recovered. The mother of the patient mentioned that the patient had had previous experiences with seizures: First time occurred at the age of 10 years (unspecified cause), second occurrence happened at 14 years of age (unspecified cause) and the third time occurred in December 2008 when the patient had her bellybutton pierced. There were no laboratories diagnostics studies performed. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Surgery; Laparoscopic surgery; Convulsion

Prex Illness:

Prex Vax Illns:

Vaers Id: **352498-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Apr-2007	Unknown		27-Jul-2009	28-Jul-2009	--	WAES0907USA03652	28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0088U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female who on 04-APR-2007 was vaccinated with first dose of GARDASIL (route not reported, lot number 655324/0088U). The registered nurse reported that the patient experienced seizure-like activity that occurred a few days after the first dose was given to the patient. It was reported that the patient received the second dose of GARDASIL (route not reported, lot number 655324/ 65863/1063U). It was unspecified if the patient had the same symptoms after she received the second dose because the registered nurse had not heard from the patient since her check-up on 08-APR-2007. The registered nurse reported that therapy with GARDASIL was discontinued on 26-OCT-2007. The patient sought medical attention by contacting the nurse. Upon internal review, seizure like activity was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352517-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	13-Jul-2009	13-Jul-2009	0	27-Jul-2009	28-Jul-2009	ME	WAES0907USA02308	28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Cognitive disorder, Dyskinesia, Hyperhidrosis, No reaction on previous exposure to drug, Presyncope, Tremor, Vomiting

Symptom Text: Information has been received from a nurse concerning a 22 year old female patient with penicillin allergy who on 07-JAN-2009 was vaccinated with the first dose of GARDASIL (lot number not reported). The patient received the second dose on 12-MAR-2009 (lot number not reported) and the third 00.5 ml dose on 13-JUL-2009 (lot number 661044/0548X). Concomitant therapy included YAZ. Subsequently, the patient experienced shaking, sweating and quivering. The patient also had jerk movement with her legs and her hands, and she was not cognitive for about 20 seconds after she received the third dose of GARDASIL. Later, the patient was given food and water, and right after that the patient had vomiting. It was unspecified if lab studies were performed. The patient stabilized after 45 minutes. It was reported that the patient had an empty stomach at the time of vaccination. The nurse also reported that the patient did not experience any adverse events after the first and second dose. Follow-up information received from the nurse on 20-JUL-2009: The lot number for all three doses is 661044/0548X. There was no concomitant therapy with the third dose. The patient's jerky movements were not tonic-clonic movements. The patient did not lose consciousness. There was no seizure happened. The vaccine was administered after the patient had a gynecology (GYN) exam and she was highly anxious. According to the nurse, the event (probably vasovagal) was considered as disabling for the 45 minutes during which the event occurred. No further information expected.

Other Meds: None

Lab Data: Unknown

History: Contraception

Prex Illness: Penicillin Allergy; Anxiety

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 352518-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	07-Jan-2009	08-Apr-2009	91	27-Jul-2009	28-Jul-2009	NM	WAES0907USA02326	19-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Anticoagulant therapy, Anxiety, Deep vein thrombosis, Dizziness, Ear congestion, Ear discomfort, Ear pain, Fatigue, Oral contraception, Otitis media, Pain, Pain in extremity, Urinary tract infection

Symptom Text: Information has been received from a physician concerning a 26 year old female with no known allergies or reported medical history who on 07-JAN-2009 was vaccinated with the first and only dose of GARDASIL (lot# 661531/1311X) 0.5 ml, I.M. route. Concomitant therapy included NECON 1/35. On 08-APR-2009, the patient experienced deep vein thrombosis. The patient was treated with anticoagulation therapy including LOVENOX and COUMADIN. Subsequently, the patient was recovered. The physician stated that "clots can be dangerous" and deep vein thrombosis was considered to be immediately life-threatening. Additional information has been requested. 8/10/09 ER Records received DOS 4/9/09. Assessment: Soleal vein thrombosis left mid calf. Patient presents with pain of left calf exacerbated by walking/movement. Stopped taking birth control pills today. 8/17/09 Consultant records received DOS 4/13/09 to 6/04/09. Assessment: Acute DVT left perineal and soleus veins. Patient reported to physican's office with left leg pain and was sent to ER for initiation of therapy for DVT. Placed on anticoagulation. Sent to consultant's office for follow-up. Presents with left calf tenderness. Urinary tract infection. left ear pain, congested, pressure and slight dizziness. Increased anxiety. Fatigue. Tympanic membranes show serous fluid accumulation.

Other Meds: NECON 1/35

Lab Data: Unknown. 8/10/09 ER Records received DOS 4/9/09. LABS and DIAGNOSTICS: Venous Doppler Study - Abnormal. 8/17/09 Consultant records received DOS 4/13/09 to 6/04/09. LABS and DIAGNOSTICS: Positive Doppler report with extension of DVT. INR 2

History: Unknown. 8/10/09 ER Records received DOS 4/9/09. Alcohol use, Smoker, UTI, Acne, HPV. 8/17/09 Consultant records received DOS 4/13/09 to 6/04/09. Urinary tract infections. Smokes.

Prex Illness:

Prex Vax Illns:

Vaers Id: **352519-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Apr-2009	27-Apr-2009	0	27-Jul-2009	28-Jul-2009	FR	WAES0907USA03263	28-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0467U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: Initial case received from the foreign Health Authority on 20-JUL-2009, documentation number 31110: A 13-year-old female patient with no medical history reported was vaccinated with the third dose of GARDASIL (lot # 0467U, batch # NG14300, intramuscular, site not reported) on 27-APR-2009. It was reported that about 1/2 hour post vaccination the female developed headache, dizziness and blood pressure of RR 92/60-64. A further 1/2 hour later headache and blood pressure 100/60-73, and further 1 hour later headache. Duration: The whole day. The next day the female still had headache, and on the third day post vaccination the female had no headache anymore. This case was classified as medically significant from the reporter. The female patient had recovered. Other business partner numbers include E2009-06113. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: blood pressure measurement, 27Apr09, 92/60-64, 1/2 hour post vaccination; blood pressure measurement, 27Apr09, 100/60-73, 1/2 hour later

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352547-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Jul-2009	23-Jul-2009	0	27-Jul-2009	31-Jul-2009	KY		31-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Paraesthesia oral, Wheezing

Symptom Text: Patient experienced problems breathing deeply, had definite wheezing per her mother and then lips started to tingle. Mother said the event probably only lasted 10 minutes from start to finish with only 2 minutes intensity. This incident occurred about 35 - 40 minutes after administration of her first injection of Gardasil vaccine. She and her mother sat on an outside bench at a college campus during the intense 1 1/2 -2 minutes until the event was over.

Other Meds: 2 Extra Strength Tylenol administered at physician's office prior to vaccine administration.

Lab Data: Patient's visit was for a routine physical exam which included a negative urinalysis, fingerstick hemoglobin of 13.7 g/dL @ 10:30 a.m. and a tuberculin skin test (10 TU PPD)intradermally to her right forearm.

History: None really. Mom told me patient had upset stomach when much younger from the antibiotic Augmentin and reacted nervously or wildly from a "tuss" medication.

Prex Illness: None. This was patient's annual physical.

Prex Vax Illns:

Vaers Id: **352548-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jul-2009	23-Jul-2009	0	27-Jul-2009	31-Jul-2009	KS	KS200908	31-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB311AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52BO41CA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Pallor, Syncope, Tinnitus

Symptom Text: Had a syncopal episode in the parking lot. Received HPV, Hep A and TDAP. Told mom that she had ringing in the ears and felt dizzy leaving the office. When she reached the parking lot she was falling down and dizzy and started to pass out. Called to the parking lot and she was awake,pale,talking and sitting on the ground. Assisted to a wheelchair and brought back to the office.

Other Meds: None

Lab Data: Blood pressure at 15:32 in the office for physical blood pressure was 143/71, after episode and back in office B/P was 94 /56

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352552-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Jul-2009	09-Jul-2009	0	27-Jul-2009	03-Aug-2009	AZ		03-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0384X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1497X	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Erythema, Presyncope, Pyrexia, Swelling

Symptom Text: VARICELLA - redness / swelling 7/10/09 GARDASIL - Dizziness, light headed - almost fainted, fever X 48 - 72 hours

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352566-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Jul-2009	15-Jul-2009	1	28-Jul-2009	03-Aug-2009	AR		03-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Pain in extremity

Symptom Text: After vaccine started having severe shin pain (B), sternal pain-

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352567-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jul-2009	21-Jul-2009	0	28-Jul-2009	04-Aug-2009	CA		04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope, Vomiting

Symptom Text: 1) Pt fainted / or passed out after vaccination 2) Vomiting (x1) afterwards.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352569-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Jul-2009	22-Jul-2009	0	28-Jul-2009	04-Aug-2009	ID		04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2914AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall

Symptom Text: Before administering vaccine patient asked to lay down for shots for fear of needles. After giving vaccines patient sat up looked i felt fine, stood up and proceeded to walk out of room. I was talking w/ patients sister when she hit wall /side down but stared conscious she was dizzy stayed for 15min drank juice and felt fine upon leaving clinic.

Other Meds: 0 Meds

Lab Data: Blood pressure: 115/73 after fall

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **352578-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	16-Jul-2009	17-Jul-2009	1	28-Jul-2009	04-Aug-2009	MD		04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0162Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Computerised tomogram normal, Dyspnoea, Hypoaesthesia, Laboratory test normal, Nausea, Orthopnoea, Pain in extremity, Tachycardia

Symptom Text: 7 hours after GARDASIL (HPV) vaccine, awoke with leg pain, numbness, Tachycardia, orthopnea & nausea. Developed shortness of breath. Labs normal, CT scan negative for P.E. Symptoms resolved.

Other Meds: Oral Contraceptive

Lab Data:

History: No

Prex Illness: None

Prex Vax Illns:

Vaers Id: **352587-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Jul-2009	16-Jul-2009	1	28-Jul-2009	04-Aug-2009	WI		04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0695Y	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2670AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	01315Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Pruritus

Symptom Text: Mom reported posterior right arm, 1 1/2 inch diameter, red, hard and itchy after receiving vaccines 7-15-09. Onset of symptoms; 7/16/09. Still with small redness today. Reports having no pain.

Other Meds: ADDERALL X 20 mg.

Lab Data: None

History: None

Prex Illness: Well check

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352594-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jul-2009	17-Jul-2009	0	28-Jul-2009	04-Aug-2009	KS		04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	0652X	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	AHAVXV285AB	0	Unknown	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB647AA	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt. with brief (< 1 minute) syncopal episode after receiving GARDASIL. Had been given HEP A & HEP B prior to GARDASIL.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 352603-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jun-2009	29-Jun-2009	0	28-Jul-2009	29-Jul-2009	FR	WAES0907USA02891	02-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0512U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Contusion, Fall, Grand mal convulsion, Haematoma, Head injury, Hypertonia, Immediate post-injection reaction, Injury, Loss of consciousness, Pupil fixed, Syncope

Symptom Text: Case reported by health authority (case n. 100804) (local case no. IT295/09). Initial report received on 15-JUL-2009. A 15 year female patient was vaccinated on 29-JUL-2009 with the second dose of GARDASIL (lot # 0512U, batch # NG22320, route and site of administration not reported). On the same day, immediately after vaccination, she felt and banged her head with loss of consciousness, presented diffuse hypertonia, fixed eyes and tonic clonic convulsion of the four limbs. The episode lasted a few seconds and the patient regained consciousness when spoken to by the physician. The episode was not critical and there was no retrograde or anterograde amnesia. On arrival at the emergency unit, the patient was vigilant, not disoriented, presented no vomiting, no amnesia, normal vital functions, normal cardiac and neurological examination. She presented eyebrow injury with hematoma sutured by a surgeon. ECG was normal. Hematology work-up was normal, EEG was negative, Neurological advice was sought and neurologist recommended hospitalization for observation. During hospitalization, clinical condition was good, without fever. NPI (neuropsychiatric inventory) and EEG (awake and sleeping) were performed and were normal. The patient had presented spasms during the previous year with EEG performed in another structure. In 2006, the patient resented frequent episodes of lipothymia induced by a rapid position changes during malaise or prolonged standing position. Cardiac and neurological examinations were normal. The patient was discharged on 03-JUL-2009 with diagnosis of cranial trauma without commotion and injury with contusion and hematoma secondary to syncope. At the time of reporting, the patient improved. The final outcome is unknown. Case is closed. Follow-up information received on 27-JUL-2009 from health authority: PET scan, CBC and psychiatric consultation were normal. Other business partner numbers include: E2009-05946. No further information is available.

Other Meds: Unknown

Lab Data: electrocardiogram, ??Jun?09, normal; electroencephalography, ??Jun?09, negative; positron emission tomography, normal; complete blood cell count, normal

History: Spasms; Malaise

Prex Illness:

Prex Vax Illns:

Vaers Id: **352604-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-May-2009	28-May-2009	0	28-Jul-2009	29-Jul-2009	FR	WAES0907USA00099	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, General physical health deterioration, Headache, Laboratory test normal, Musculoskeletal stiffness, Nausea, Neck pain, No reaction on previous exposure to drug, Pain in extremity, Pyrexia, Vomiting

Symptom Text: Case received from Health Authority on 29-JUN-2009 under HA reference no. PEI2009013923. It was reported that a 13 year old female patient was vaccinated with a third dose of GARDASIL (lot # not reported) into the left deltoid muscle on 28-MAY-2009. 4 hours post vaccination, the patient developed fever (> 40 C) and headache. 7 hours post vaccination she experienced recurrent vomiting. The patient was hospitalized on unspecified date. Serology showed no pathological findings, meningitis was ruled out. The patient recovered from vomiting after two days, from fever and headache after three days. Previous two doses of GARDASIL were well tolerated. Follow up information was received on 17-JUL-2009. The hospital report of the paediatric hospital (28-MAY-2009 to 31-MAY-2009) was provided. At admission on 28-MAY-2009, the patient suffered from fever, headache and pain in limbs (verbatim, PEI coded infection). Previously she was treated with a single dose of ASPIRIN by her parents and she had presented to an other hospital before where she had been treated with sodium chloride (NaCl) infusion. Then she was transferred to the paediatric hospital and suffered additionally from abdominal pain, neck pain, nausea, vomiting, neck stiff and was in a reduced general condition. By several investigations, meningitis was ruled out. Laboratory values showed no pathological findings. After infusion therapy for two and a half days together with antipyrines, the symptoms improved. On 31-MAY-2009, the patient was discharged, completely recovered. The hospital physician considered the event as related to vaccination. Other business partner numbers include E2009-05405. No further information is available. Case closed.

Other Meds: Unknown

Lab Data: temperature measurement, > 40 C

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352605-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Apr-2009	11-May-2009	36	28-Jul-2009	29-Jul-2009	FR	WAES0907USA03150	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1941U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Optic neuritis, Scotoma, Vision blurred, Visual evoked potentials abnormal

Symptom Text: Case received from the Health Authorities on 20-JUL-2009 under the reference numbers AN20090365 AB200940373. A 17-year-old female patient with no relevant medical history and no concomitant treatment received the third dose of GARDASIL (lot #1941U, batch # NJ17150) via intramuscular route on 05-APR-2009. She had received the first dose and second dose via intramuscular route in October and December 2008. The morning of 11-MAY-2009, the patient developed a central scotoma in the right eye associated not painful associated with blurred vision. Ophthalmological work-up were normal on 14-MAY-2009. Retinal computed axial tomography (CT) scan was normal and retinal angiography was normal on 18-MAY-2009. The following work-up were normal on 19-MAY-2009: Complete blood count, platelets, erythrocyte sedimentation rate and toxoplasmosis serology. On 20-MAY-2009 neurological examination was normal except for central scotoma. Visual evoked potentials showed a latency asymmetry of the right optic nerve. Cerebral magnetic resonance imaging (MRI) performed on 02-JUN-2009 was normal. Fine cut magnetic resonance imaging (MRI) centered on the optic nerve performed on 13-JUN-2009 did not show any anomaly. In the weeks before symptomatology. There was no infectious syndrome. The patient was hospitalized from 19 to 31-MAY-2009. She was treated with SOLUMEDROL in the context of an optic neuritis retrobular. On 08-JUN-2009, there was a slight improvement but central scotoma persisted. Visual evoked potentials showed that the asymmetry had resolved. At the time of reporting, the patient had not yet recovered. The Health authorities assessed the causal relationship between the reported reactions and vaccination as "doubtful" according to the foreign method of assessment. Other business partner numbers include E2009-06137. No further information is available.

Other Meds: None

Lab Data: computed axial tomography, 14May09, Normal; ophthalmological exam, 14May09, Normal; diagnostic laboratory test, 18May09, retinal angiography; diagnostic laboratory test, 19May09, Complete blood count normal; neurological examination, 20May0

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **352606-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Jun-2009	02-Jul-2009	7	28-Jul-2009	29-Jul-2009	FR	WAES0907USA03710	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1201U	1	Unknown	Intramuscular	
	HEP	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Condition aggravated, Hypoaesthesia, No reaction on previous exposure to drug, Pain, Paresis, Urinary retention

Symptom Text: Information has been received from a pediatrician concerning a 17 year old female patient who received the first dose of GARDASIL on an unspecified date and was well tolerated and on 25-JUN-2009 was vaccinated with the second dose of GARDASIL (lot#1201U/batch# NG29090) intramuscularly with a dose of RECOMBIVAX (manufacturer unknown) intramuscularly. Concomitant therapy included hormonal contraceptives (unspecified). On 02-JUL-2009 the patient experienced lumbago with an augmentation of pain since 06-JUL-2009. She was treated with Ibuprofen 1800 mg per oral route daily from 02-JUL-2009 to 06-JUL-2009. On 08-JUL-2009, she developed hypoaesthesia of the right foot and pareses of extension and flexion of right foot and right toes. On 12-JUL-2009, she experienced retention of urine. A herniated vertebral disc was excluded by MRI: EMG showed no denervation, but reduced interference pattern. Nerve conduction velocities of both peroneal nerves were normal. The patient recovered spontaneously from urinary retention, but not from pareses and hypoaesthesia and the outcome of lumbago was unknown. Lumbago, hypoaesthesia, pareses, urinary retention and condition aggravated were considered as other important medical events by the reporter. Other business partner numbers include: E2009-06099.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: electromyography, 12?Jul09, no denervation; magnetic resonance imaging, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 352607-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Jul-2009	14-Jul-2009	0	28-Jul-2009	29-Jul-2009	FR	WAES0907USA03711	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK19200	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Bradycardia, Fall, Nausea, Pulse pressure decreased, Shock, Syncope

Symptom Text: Information has been received from a health authority (case number 101317) through a foreign agency (local case number IT303/09) concerning a 15 year old female patient who on 14-JUL-2009 was vaccinated with the first dose of GARDASIL intramuscularly, site of administration was not reported. There was no concomitant medication. Two minutes after vaccination on 14-JUL-2009, she presented lipothymia with fainting leading to fall and shock of the head and back, abdominal pain, nausea and arthralgia. An ambulance was called and the patient was transported to Emergency Unit, followed by hospitalization then prolonged hospitalization. The patient had blood pressure at 80 mmHg, weak pulse and bradycardia. Clinical control with blood pressure was performed. The patient was lying, received water and sugar and did not require medication. On 14-JUL-2009, the patient fully recovered. Case is closed. Other business partner numbers include: E2009-06093.

Other Meds: None

Lab Data: blood pressure measurement, 14Jul09, 80 mmHg

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 352608-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Jul-2009	09-Jul-2009	0	28-Jul-2009	29-Jul-2009	FR	WAES0907USA03714	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1113U	0	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Borrelia infection, Facial palsy

Symptom Text: Information has been received from a general practitioner concerning a 12 year old female patient who on 09-JUL-2009 was vaccinated with the first dose of GARDASIL (Lot # 1113U, batch #NH04240) into the left upper arm and with a first dose of (NEISVAC-C) into the right upper arm. On 09-JUL-2009 in the evening, the patient experienced peripheral facial palsy and was admitted to the hospital. The reporter was contacted by phone on 20-JUL-2009 in order to gather additional information. Meanwhile, CSF exam had revealed borrelia infection. Being aware of this new information, the reporter does no more consider the event being possibly related with the vaccines. Other business partner numbers include: E2009-06088.

Other Meds: Unknown

Lab Data: cerebrospinal fluid culture, revealed Borrelia infection

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352612-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	13-Jul-2009	13-Jul-2009	0	28-Jul-2009	29-Jul-2009	FR	WAES0907CAN00057	29-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0695X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia facial, Localised oedema, Paraesthesia

Symptom Text: Information has been received from a nurse concerning a 25 year old female who on 13-JUL-2009 was vaccinated with the first dose of GARDASIL, batch # NJ17110/lot # 661046/0695X. On 13-JUL-2009 the patient experienced numbness right side of chin, tingling near the navel and right sided chin edema (there was no redness or skin eruption). On approximately 14-JUL-2009 the patient recovered from numbness right side of chin, tingling near the navel and right sided chin edema (the nurse reported that the symptoms resolved within 12 hours). Numbness right side of chin and tingling near the navel were determined to be important medical events based on foreign agency requirements. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352615-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Jul-2009	13-Jul-2009	0	28-Jul-2009	04-Aug-2009	NC	NC09031	04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB312AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Subcutaneously	
	VARCEL	MERCK & CO. INC.	0227	0	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site warmth

Symptom Text: Pt experiencing erythema, warmth, and tenderness at injection site - R arm where varicella vaccination given. Sx x 3days not improving.

Other Meds: MENTAX; DIFLUCAN

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **352629-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Jul-2009	28-Jul-2009	0	28-Jul-2009	31-Jul-2009	LA		31-Jul-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2910AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	UF456AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0336Y	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	1497X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Cold sweat, Nausea, Pallor

Symptom Text: Tdap, Varicella, MCV4, & Gardasil were completely administered at approximately 1:50 p.m. on 7/28/09; When the family was checking out at the clerk's window, the patient told her mother she felt weak. The patient leaned against the wall and the mother assisted her to the floor. When the nurse arrived at the front, the patient was awake, alert, & oriented. She was clammy and c/o nausea. The nurse assisted her to the bathroom and the patient sat down. B/P was 72/46, Respirations 14, regular; Skin cool and damp, pale. After about 15 minutes, patient began feeling better, color had returned.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **352640-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Jul-2009	27-Jul-2009	0	28-Jul-2009	04-Aug-2009	IN		12-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Allergy to vaccine, Chest pain, Diarrhoea, Dyspnoea, Feeling hot, Hyperaesthesia, Hypersensitivity, Injection site nodule, Nausea, Oedema peripheral, Pain in extremity, Vomiting

Symptom Text: Feels warm though no fever. Edema in hands / feet skin all over body was sensitive to touch. Steroids started 7/28/09 and ZANTAC. 9/1/09 PCP records received for 7/27/09 to 7/29/09. WCC 7/27/09 with vax given. Returned 7/28/09 with c/o allergic reaction to Gardasil. Pt c/o dyspnea, pain and edema in hands and feet, chest pain,feels hot despite normal temp. Also nausea, vomiting and diarrhea noted in ROS. Pain with palpation to extremities. 7/29/09 reports knot at injection site. Skin improved. Tx: Benadryl and NSAIDS. 1/6/10: PCP Record received for date of service 7/27/09. Hx of Bee sting allergy, epi pen refill given.

Other Meds:

Lab Data:

History: No PMH: Bee sting allergy. Obesity. Plantar fascitis. swelling/edema hands and feet

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352659-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	21-Jul-2009	21-Jul-2009	0	29-Jul-2009	05-Aug-2009	MO		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Immediate post-injection reaction, Loss of consciousness, Pallor

Symptom Text: Patient c/o lightheadedness, "feeling faint" directly after vaccination (had no c/o after 1st shot) Pt. became diaphoretic, pale-reclined with feet up, cool compresses-color returned to face. "felt as if lost consciousness" fro a few seconds. Pt. had eaten breakfast and exercised prior to coming in.

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 352666-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	08-Jun-2009	Unknown		29-Jul-2009	30-Jul-2009	FL	WAES0907USA03645	30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Intensive care, Tic, Viral infection

Symptom Text: Information has been received from a physician concerning the physician's daughter with not reported drug reactions/allergies and medical history who on 08-JUN-2009 was vaccinated with a first dose of GARDASIL (0.5ml, route unspecified). The physician stated that her daughter had a virus which resulted in a "post-viral tic" and she stayed in the hospital in Intensive care unit (ICU) for two days (from 18-JUL-2009 to 20-JUL-2009). The physician felt that the patient's virus was not related to the GARDASIL. The patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352667-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		29-Jul-2009	30-Jul-2009	--	WAES0907USA03675	30-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Paralysis, Sensory loss

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old nurse practitioner female (her daughter in law) with no reported drug reactions/allergies and medical history who was vaccinated IM with 0.5ml first dose of GARDASIL (date and lot numbers not reported). There was no concomitant medication reported. The nurse reported that "a few hours after receiving her first dose of GARDASIL, the patient experienced lost feeling in her extremities. "It was a paralysis of sorts". Subsequently, the patient went to ER (hospital unspecified). The ER doctors determined that it was due to the vaccine". "After several hours, the adverse event resolved". "They ran a bunch of test in the ER" (test and results not specified). Upon internal review, paralysis of sorts was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: laboratory test, "bunch of test in ER"

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352674-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	27-Jul-2009	27-Jul-2009	0	29-Jul-2009	03-Aug-2009	IA		03-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0670Y	0	Left leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Computerised tomogram abnormal, Concussion, Ear haemorrhage, Ear injury, Excoriation, Fall, Head injury, Headache, Syncope

Symptom Text: Patient had fainting episode shortly after the shot. She fell and hit her R shoulder and R ear--she was placed lying down on exam table. Given water and tylenol; she felt better after 20 minutes. She declined any xrays or ER. Wanted to go back to work. R clavicle mild abrasion, R pinna-blood from earring, stopped on own. Headache continued so patient had a head CT scan. It was positive for concussion, she was given head injury precautions.

Other Meds: Alesse oral contraceptive

Lab Data:

History: Allergy to Penicillin (event unknown) and hives with Sulfa drugs.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352675-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jul-2008	28-Jul-2008	7	29-Jul-2009	03-Aug-2009	MA		03-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Palpitations, Paraesthesia

Symptom Text: At yearly physical this year 7/22/07, Uncle and patient reported that 1 week after her first HPV Vaccine was administered on 7/21/08, she began having periods of shortness of breath, dizziness, hand and feet tingling and palpitations with physical activity and exercise. She had never had this difficulty prior to the HPV vaccine and had a history of being physically active in dance classes4 d/ week and playing softball. The symptoms finally resolved in January 2009. Patient and Uncle reported these symptoms tome at her yearly physical on 7/22/09.

Other Meds:

Lab Data: Chest Xray, EKG and Echocardiogram were normal.

History: GERD

Prex Illness: None.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352684-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Jul-2009	28-Jul-2009	6	29-Jul-2009	04-Aug-2009	PA		04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	00874	3	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling

Symptom Text: Received HPV #3 on 7/22/09. About 1 week later developed swelling of lateral part of lower lip. No skin rashes

Other Meds: Benzaclin gel, Clotrimazole cream

Lab Data: nonw

History: none

Prex Illness: acne, tinea

Prex Vax Illns: lip swelling~HPV (Gardasil)~3~13~In Patient

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352689-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Mar-2009	06-Mar-2009	1	29-Jul-2009	04-Aug-2009	MD		04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: bilateral arm rash

Other Meds: none

Lab Data:

History: stadol

Prex Illness: none

Prex Vax Illns:

Vaers Id: **352704-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Jul-2009	20-Jul-2009	11	29-Jul-2009	10-Aug-2009	FL		10-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1497X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blister, Headache, Oropharyngeal pain, Pyrexia, Rash, Varicella

Symptom Text: Pt received vaccine - at above clinic on 7/9/09 - - 7/20/09 start with H/A sore throat - - to high fever - around 102. Rash - to blister covering body.

Other Meds:

Lab Data: Saw Dr on 4/23/09; No lab work - Issued Rx Doxephen - Told patient had chicken pox

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 352712-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Jun-2009	22-Jun-2009	0	29-Jul-2009	05-Aug-2009	KY		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives after injection #1 Gardasil. 1 1/2 hr after given vaccine- hives developed- pt has hlo hives and they did resolve after 2 doses of Benadryl.

Other Meds: PRN asthma inhaler.

Lab Data:

History: Asthma; hlo hives.

Prex Illness: No complaints

Prex Vax Illns:

Vaers Id: **352713-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Jul-2009	28-Jul-2009	0	29-Jul-2009	05-Aug-2009	IA	IA090011	05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB350AA	0	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB737AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Gaze palsy, Syncope

Symptom Text: After administering vaccines listed below, patient continued to sit in chair and after approximately 2 minutes patient stated she felt dizzy. After about 10 seconds her eyes rolled back and she fainted. Patient remained in chair with RN's monitoring her. Patient started responding within 2-3 minutes. Her mother was called and she came and picked her up drove her home.

Other Meds:

Lab Data:

History: BACTRIM

Prex Illness:

Prex Vax Illns:

Vaers Id: **352714-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-Jul-2009	29-Jul-2009	0	29-Jul-2009	05-Aug-2009	FL		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0695Y	1	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2928AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0312Y		Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB342DA	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Fall, Loss of consciousness, Syncope

Symptom Text: 1-2 seconds after immunizations administered child became unconscious and fell back on the exam bed. Her respirations were 22/sec HR was 88 BPM pulse strong, PERRLA, she regained consciousness in 20 seconds, cried, but did not remember fainting. Walked out of office well. No jerking noted.

Other Meds: None

Lab Data: None

History: None; Has had near -syncope before once or twice.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **352717-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	16-Jul-2009	Unknown		29-Jul-2009	06-Aug-2009	WI		06-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Period delayed 3 days after 2nd dose and 6 days after 3rd dose. Parent requested this be reported.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352730-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	17-Jun-2008	Unknown		30-Jul-2009	31-Jul-2009	FR	WAES0907USA04419	31-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1172U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Alopecia areata, Urinary tract infection

Symptom Text: Information has been received from a gynaecologist concerning a 22 year old female who on 17-JUN-2008 was vaccinated intramuscularly with the first dose of GARDASIL (lot# 1172U, batch# NH13130) into the left arm. Concomitant therapy included MINISISTON. In 2008, on an unspecified date post vaccination the patient developed diffuse hair loss at first, followed by alopecia areata up to generalized hair loss at the time of reporting. Additionally she experienced relapsing urinary tract infections which were treated with antibiotics. Dermatological and endocrinological examination showed no pathologies. Despite ongoing symptoms the patient received a second dose of GARDASIL (lot #1115U, batch# NH33310) on 20-AUG-2008 and a third dose of GARDASIL (lot# 1050U, batch# NH32130) on 12-JAN-2009. At the time of reporting symptoms were ongoing. Hair loss and urinary tract infection were considered to be other medically important condition by the reporter. Other business partner numbers included: E 2009-06129. Additional information has been requested.

Other Meds: MINISISTON

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352731-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Jul-2009	10-Jul-2009	4	30-Jul-2009	31-Jul-2009	FR	WAES0907USA04424	31-Jul-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1282U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Vestibular neuronitis

Symptom Text: Case received from a health care professional in country on 20-JUL-2009. It was reported by a pediatrician that a 17-year old (also reported as 18 year old) female patient was vaccinated with a first dose of GARDASIL (Lot:1282U, Batch: NH33500) IM into the upper arm on 06-JUL-2009. On 10-JUL-2009 the patient was hospitalized and vestibular neuronitis was diagnosed. Magnetic resonance imaging (MRI), electroencephalography (EEG) and cerebrospinal fluid culture (CFS) showed normal results. Symptoms improved and the patient was discharged on 17-JUL-2009. At the time of reporting the patient has not completely recovered. Other business partner numbers include E2009-06107.

Other Meds:

Lab Data: magnetic resonance imaging, 10?Jul09, showed normal results; electroencephalography, 10?Jul09, showed normal results; cerebrospinal fluid culture, 10?Jul09, showed normal results

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **352744-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jul-2009	23-Jul-2009	0	30-Jul-2009	06-Aug-2009	ME		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Myalgia, Pyrexia, Rhinorrhoea

Symptom Text: Low grade fever, muscle aches, site erythema and tenderness, increase resp mucus. Pos - vax adverse reaction, pos mild URI and premenstrual condition.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **352748-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	16-Jul-2009	19-Jul-2009	3	30-Jul-2009	05-Aug-2009	NE		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash erythematous, Rash vesicular

Symptom Text: Red raised rash on neck, legs, arms "looks like chicken pox!"

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **352760-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Jul-2009	27-Jul-2009	0	30-Jul-2009	06-Aug-2009	KY		06-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB350AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: 10:45 AM fainted - ice pack, counseling

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352761-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Jul-2009	24-Jul-2009	0	30-Jul-2009	06-Aug-2009	WV		06-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Pallor

Symptom Text: Shortly after receiving vaccine, while sitting on table she became ashes in color, used ammonia inhaler but she passed out to lying down position on table. Ice was applied to neck and forehead. Mother was present. I was forewarned as pt. fainted with 1st HPV vaccine. About 20 minutes later pt. stated she was ok, left with family to go eat.

Other Meds: NK

Lab Data: None

History: NK

Prex Illness: NK

Prex Vax Illns: 1/2/09~HPV (Gardasil)~1~16~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352774-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Jul-2009	24-Jul-2009	0	30-Jul-2009	05-Aug-2009	WI		05-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0376Y	0	Right arm	Subcutaneously	
TDAP	SANOFI PASTEUR	C2773A	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2906AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Feeling hot, Immediate post-injection reaction, Pallor

Symptom Text: Immediately following administration of vaccines, client became pale, hot, and dizzy. BP 74/40. Had client place head between knees, cold pack applied to back of neck, juice given. 10 minutes later BP 90/72, HR 62. Client escorted by RN to another room to rest and have another juice. Health aid remained with client. BP 118/78 15 minutes later. Client felt fine, color back in face, no longer hot or dizzy. Client driven home by her friend.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **352776-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Jul-2009	27-Jul-2009	0	30-Jul-2009	05-Aug-2009	NY		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	06634	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0381X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Came in for Gardisil #3. Layed down before shot administered to right arm. After 5 mins patient experienced syncope episode while laying on table. Feet were elevated, cool compress to head and back of neck. Kept and monitered for approx 30 mins.

Other Meds: no

Lab Data: none

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **352777-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jul-2009	21-Jul-2009	0	30-Jul-2009	05-Aug-2009	MO	MO-2009-16	05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2868AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Nausea, Pallor, Syncope, Vomiting

Symptom Text: Patient recedived vaccines. While patient was leaving the building she fainted. Patient quickly awakened, but was confused for a short time. Patient then had nausea/vomiting for a short time. Patient was given a cool wash cloth and door opened for fresh air. Blood pressure obtained 98/62. Patient's pink color started to return. Patient given sprite and peanut butter crackers after nausea and vomiting gone. Patient said she was feeling better. She then was stood up after approximately 15 minutes adn sat in a chair and recovered fully before leaving with her mom.

Other Meds:

Lab Data:

History: none known

Prex Illness: none known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352784-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-Jul-2009	30-Jul-2009	9	30-Jul-2009	05-Aug-2009	FL		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2922AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0345Y	0	Left arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B036BA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB312AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: PATIENT RECEIVED VZV ON 7-21-09 AND DISCOVERED SHE WAS PREGNANT ON 7-30-09.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352789-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jul-2009	29-Jul-2009	0	30-Jul-2009	05-Aug-2009	KS		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2990AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	00874	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0644Y		Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Pain, Pruritus

Symptom Text: Less than 8 hours later right leg itching, burning and pain

Other Meds: insulin

Lab Data: none

History: DM-I

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352808-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Jul-2009	29-Jul-2009	0	30-Jul-2009	06-Aug-2009	CA		06-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3070AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U29149A	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0100X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Patient almost fainted.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352809-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Apr-2009	Unknown		30-Jul-2009	06-Aug-2009	SD		21-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB262AA	1	Right arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHAVB262AA	2	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	U2590BA	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2825AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: HPV vaccine given, no adverse events but patient returned for 2nd injection & said was pregnant when got 1st dose

Other Meds: Prenatal vitamin

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352828-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Jul-2009	14-Jul-2009	0	31-Jul-2009	07-Aug-2009	CA		07-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Suture insertion, Syncope

Symptom Text: 18 year old female became dizzy and fainted after administering GARDASIL vaccine was taken to the hospital where she got staples on her head.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 352842-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Mar-2009	12-Jul-2009	127	31-Jul-2009	03-Aug-2009	FR	WAES0907USA04437	03-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1883U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Anorexia, Endotracheal intubation, Eye movement disorder, Fatigue, Glasgow coma scale, Grunting, Incontinence, Intensive care, Mutism, Neurological decompensation, Parenteral nutrition, Respiratory disorder

Symptom Text: Information has been received from a resident internist in charge of the patient at the pediatric intensive care unit concerning a 15 year old female who on 13-JAN-2009 was vaccinated with the first dose of GARDASIL (lot# 1883U, batch# NH50490). On 07-MAR-2009 the patient received the second dose of GARDASIL (lot# 1883U, batch# NH47610). The patient had no personal or family neurological history. On 12-JUL-2009, i.e. approximately 4 months after vaccination, the patient presented with a severe fatigue, anorexia and then evolved to mutism. Afterwards, she experienced sphincterian disorders, then neurological and respiratory deterioration associated with a collapse of Glasgow coma scale. The patient was intubated for 72 hours. Magnetic resonance imaging (MRI) was performed on 20-JUL-2009. Acute disseminated encephalomyelitis was diagnosed. On 23-JUL-2009, the patient presented a complete deficit of lower limbs, a complete mutism associated with a few gruntings, and an inconstant tracking eye movement. The patient was treated with antibiotics. She was initially treated with ZOVIRAX, but the treatment was stopped due to lack of arguments in favour of herpetic infection. The patient was under parenteral alimentation. According to the internist, the usual causes for acute disseminated encephalomyelitis were vaccine or viral infection. The patient should have received the third dose of GARDASIL 15 days before the first clinical signs. However as the vaccine was not administered, "Vaccine etiology" was consequently ruled out. Results for viral serologies were expected. To be noted that the case was initially reported to the sales representative by a gynecologist who told her about a 15-year-old female patient who was "between life and death" after receiving the third dose of GARDASIL. At the time of reporting, the patient had not recovered. Other business partner numbers include E200906299.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, 20Jul09, Acute disseminated encephalomyelitis was diagnosed

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 352843-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Jul-2009	Unknown		31-Jul-2009	03-Aug-2009	CA	WAES0907USA04814	28-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TD	UNKNOWN MANUFACTURER	UF471AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1130X		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2918AA		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Pancreatitis, Upper respiratory tract infection, Venous thrombosis, Viral infection

Symptom Text: Information has been received from a medical assistant concerning a female patient who was vaccinated with GARDASIL (vaccination date, dose number and lot number not reported). The patient developed pancreatitis after vaccination (date unspecified). Medical attention was sought by office visit. It was unknown if there were lab studies performed. At the time of the report, the patient not recovered. Upon internal review, pancreatitis was determined to be an other important medical event. Additional information has been requested. ```DC summary and hospital records received 1/15/10 for dates 7/24/09 to 7/28/09, pt then transferred to another hospital. DX: acute pancreatitis, rt upper extremity venous thrombosis. CC: 1 month h/o viral infections, URI, 1 day h/o vaccination to meningococcal, gardasil, and tetanus, acute onset of LUQ abdominal pain. Assessment: mild tenderness of abdomen upon palpation, ```Hosp admitting summary received 2/9/10 for date 7/28/09. DX: acute pancreatitis secondary to gardasil vax, also risk factor was recent viral infection and alcohol use, but less likely reasons, RUE thrombophlebitis secondary to IV infiltrate. CC: pt transferred from another hospital for further care of acute pancreatitis, right superficial thrombophilebitis in the UE. Pt initially admitted to prev hospital for abdominal pain. During pt stay at prev hospital, IV infiltrated in RUE and US showed nonocclusive thrombus. During this stay from medical history pt had 1 month h/o viral infection recently and 1 day h/o gardasil vax. Pt had recent trip to Mexico where pt consumed alcohol x 1 ```MR received 2/24/10 for date 7/23/09. DX: Normal wellness exam. CC: school physical history exam. month ago.

Other Meds: Unknown

Lab Data: Unknown ```DC summary and hospital records received 1/15/10 Diag/labs: CT abnormal-enlarged pancreatic tail, RUE venous Doppler(+)thrombus, amylase 330(H), lipase 1370(H), CBC diff abnormal.

History: Unknown ```DC summary and hospital records received 1/15/10 PMH: oral contraception use, acne.

Prex Illness:

Prex Vax Illns:

Vaers Id: **352879-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-May-2009	05-May-2009	0	31-Jul-2009	03-Aug-2009	FR	WAES0907USA02788	03-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1697U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse via CSL as part of a business agreement for the pregnancy Registry for GARDASIL, concerning a 17 year old female with no pertinent medical history, any risk factor (no diabetes, hypertension, no alcohol or smoker) and any history of previous pregnancies, who on 05-MAY-2009 was vaccinated with a dose of GARDASIL (Lot: 1697U, Batch: NH48330) while she was three weeks pregnant (last menstrual period: 14-APR-2009 and her estimated delivery date was 22-JAN-2010). Additional information has been received from the nurse who informed that the patient has voluntary terminated her pregnancy. The nurse reported that the outcome had nothing to do with GARDASIL (administration. At the time of reporting on 20-JUL-2009, the patient's status was unknown. Upon internal review voluntary terminated pregnancy was considered as other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 17Apr09); Non-smoker

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352883-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		31-Jul-2009	03-Aug-2009	FR	WAES0907USA03792	03-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervix carcinoma

Symptom Text: Information has been received from a television media source concerning a 21 year old female who "two years ago" (in approximately 2007) was vaccinated with GARDASIL. Subsequently the patient experienced cervical cancer. The outcome was not reported. A physician reported the patient may have been exposed to the virus prior to being vaccinated with GARDASIL. No further information was provided. Upon internal review, cervical cancer was considered to be an other important medical event.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352891-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Jul-2009	30-Jul-2009	0	31-Jul-2009	04-Aug-2009	IL		04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	05024	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cyanosis, Loss of consciousness, Pallor, Vomiting

Symptom Text: Incident occured 7-30-09. After administration of HPV and Varicella vaccine,client was escorted to a chair to be obserbed for 15 min. While seated in the chair, mother obserbed that the client was pale, lips cyanotic. Client proceeded to lose conciousness briefly (30 sec) vomited repeatedly approximately 5x.

Other Meds: unknown

Lab Data:

History: unknown

Prex Illness: n/a

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352895-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-Jul-2009	30-Jul-2009	1	31-Jul-2009	05-Aug-2009	TX		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3246BA	5	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB287AB	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1497X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2909AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	05954	1	Left leg	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth, Wrong technique in drug usage process

Symptom Text: Patient received hpv vaccine on 7/29/09 on right arm. Reaction on 7/30/09 about 24 hours after vaccine was administered. Area has swelling, is red and warm to touch. Redness is about 2 inches in diameter and 4 inch in length. Nurse documented vaccine given IM, client's mother states vaccine was given sub Q. Reaction is in the back part of the right arm.

Other Meds: No medications taken by client

Lab Data: Not known at this time

History: No existing illnesses

Prex Illness: No illness at time of vaccination

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352897-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Jul-2009	31-Jul-2009	0	31-Jul-2009	05-Aug-2009	MD		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Swollen tongue, Urticaria

Symptom Text: Patient received Gardasil immunization at approximately 12:15 pm. Stayed at doctor's office for 20 minutes following the immunization. At approximately 1:30 pm received call from patient's mother stating she was having a swollen tongue and hives on the right side of her face. Patient has history of significant allergies. Requested that mom give patient benadryl and to monitor for changes. Patient's mom was instructed to use epi-pen and call 911 if the patient's symptoms did not improve after benadryl.

Other Meds: None

Lab Data: None

History: Pre-existing asthma and allergies causing anaphylaxis after ingestion of milk or milk products, penicillin, and ibuprofen/NSAIDs.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352908-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	31-Jul-2009	31-Jul-2009	0	31-Jul-2009	05-Aug-2009	PA		05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	1104X	5	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3250AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0455Y	0	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Pt was given the following injections: Adacel (Tdap), Gardasil (HPV), and Hep B. She c/o's feeling suddenly light-headed/dizzy/nauseated. She was assisted onto the exam table to lie down until sx's subsided

Other Meds:

Lab Data: NA

History: NA

Prex Illness: NAUSEA, VOMITING, DIARRHEA, HEADACHE

Prex Vax Illns:

Vaers Id: **352910-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Jul-2009	31-Jul-2009	1	31-Jul-2009	06-Aug-2009	WA		07-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2614AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0596Y	1	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B04BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain, Injection site pruritus, Injection site swelling, Injection site warmth

Symptom Text: PT'S MOTHER STATED THAT ABOUT 24HRS AFTER ADMINISTRATION OF VACCINE, SHE NOTICED REDNESS AND SWELLING AT VACCINATION SITE. VACCINE (VARIVAX) ADMINISTERED 7/30/09 AT ABOUT 1030HRS. PT C/O SORENESS AND ITCHING AT SITE. NURSE ASSESSED ABOUT 35MM INDURATION, REDNESS AND MINIMAL WARMTH AT VACCINE INJECTION SITE. PT DENIES ANY OTHER SX'S AND NO OTHER SX'S ASSESSED BY NURSE AT TIME PT REPORTED ADVERSE EVENT TO ADMINISTRATION FACILITY (FAMILY MEDICINE DEPT).

Other Meds:

Lab Data:

History: HX OF ASTHMA. DENIES ANY OTHER ALLERGIES ARE MEDICAL CONDITIONS PER PT'S MOTHER

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352921-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	27-Mar-2008	27-Mar-2008	0	02-Aug-2009	10-Aug-2009	IA		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Right arm	Unknown	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Anal fissure, Arthralgia, Asthenia, Back pain, Bronchitis, Bruxism, Cervical dysplasia, Cervicitis, Chest discomfort, Clumsiness, Confusional state, Constipation, Diarrhoea, Disturbance in attention, Dizziness, Dysplasia, Dysuria, Ear infection, Ear pain, Fatigue, Flank pain, Haematochezia, Headache, Hyperhidrosis, Hypersomnia, Influenza, Irritable bowel syndrome, Kidney infection, Lymphadenopathy, Myalgia, Nasopharyngitis, Neck pain, Odynophagia, Oral contraception, Oropharyngeal pain, Otitis media, Pain, Pain in extremity, Palpitations, Pelvic pain, Pharyngitis, Pharyngitis streptococcal, Photophobia, Productive cough, Pruritus, Pyelonephritis, Rash, Rhinorrhoea, Sinus disorder, Skeletal injury, Smear cervix abnormal, Urinary tract infection, Vaccine positive rechallenge, Vaginal haemorrhage

Symptom Text: After first gardasil shot on 03/27/08 my symptoms included: Pain in my arm, dizziness, acute pharyngitis, sore joints and mucles. After my 2nd Gardasil shot on 05/27/08 my symptoms were arm was sore, dizzy, weak, fatigued, whole body ached, severe lower pelvic pain a couple times, Flue off and on, colds, acute pharyngitis a few times, ear aches and infections, sore joints, back and neck pain, headaches off and on, IBS with constipation and bouts of diarrhea,had colonoscopy done, frequent UTI's, kidney infection, hard to concentrate, confusion, had rash on left shoulder for awhile then went away,sensitivity to light, racing heart sometimes, when dizzy my palms sweat, I become clumsy and heart races, grinding teeth, and on 05/29/09 went to OBGYN for Yearly Pap smear and every year it has been normal, no problems but this year, one year after I had my second Gardasil shot the results came back as abnormal. Showed HIGH GRADE SQUAMOUS INTRAEPITHELIAL LESION moderate dysplasia CIN 2. Doctor then gave me a colposcopy on 6/26/09 my protien level in urine was high +3 as well said I had ACUTE CERVICITIS. Then had Leep Biopsy done on 7/15/09 for the HIGH GRADE SIL the results were, I had HIGH GRADE SQUAMOUS INTRAPITHELIAL LESION CIN 3 SEVERE DYSPLASIA. They removed all abnormal cells. now bleeding on and off. Been on antibiotics 6 different times in one years time since I had the Vaccine. Never got sick before the shot. I believe these symptoms are caused by the Gardasil Vaccine. I believe I might have something wrong with my immune system or nervous system now. 8/5/09 PCP medical records received DOS 08/16/06 to 7/20/09. Assessment: Acute Cervicitis. High Grade Squamous Intraepithelial Lesion (CIN 3, Severe Dysplasia of Cervix. Patient presents with sore throat, productive cough, and sinus drainage. Oral contraceptives. Pharyngitis. Ear ache. Hurts to swallow. Neck anterior lymphadenopathy. Strep throat. Fatigue, headaches, needing more sleep at night. Bronchitis, chest discomfort with hx of rib contusions. Constipat

Other Meds: Birth control pills thats it.

Lab Data: pap smear,leep biopsy, colposcopy, CBC was normal but Glm filtration Rate, Es was 70 normal is 60,strep screen negative, mono screen negative,colonoscopy, UA showed glucose at 250, bilirubin LARGE, ketones 15, specific gravity <1.005, blood

History: none. 8/5/09 PCP medical records received DOS 08/16/06 to 7/20/09. Eye surgery. Caffeine use. Pelvic pain. Oral contraceptives. Penicillin allergy. Hives. Bacterial vaginosis

Prex Illness: none

Prex Vax Illns:

Vaers Id: **352926-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Jul-2009	Unknown		31-Jul-2009	07-Aug-2009	CA		07-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0492Y	1	Right arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336DA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1497X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Pallor

Symptom Text: - L.O.C for 2 sec. - Paleness in face * Treatment -> lay down with elevated legs

Other Meds:

Lab Data:

History: NKDA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352933-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Jul-2009	22-Jul-2009	0	31-Jul-2009	07-Aug-2009	FL		07-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF455BA	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2909PA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: Dizziness and headache.

Other Meds:

Lab Data: None

History: None

Prex Illness: H/o headaches (+)

Prex Vax Illns:

Vaers Id: 352986-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Mar-2008	10-Sep-2008	193	03-Aug-2009	04-Aug-2009	KS	WAES0907USA04864	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal disorder, Streptococcal identification test positive

Symptom Text: Information has been received from a Registered Nurse (R.N) and a Physician for the pregnancy registry for GARDASIL concerning a 17 year old female patient who was a heavy smoker, with anemia during her pregnancy which was treated with oral iron supplements who in March 2008 (also reported as almost 2 years ago) was vaccinated with the first dose of GARDASIL (Lot # not reported). Concomitant therapy included prenatal vitamins (unspecified) and FLUVIRIN. It was reported that the patient became pregnant. The patient's last menstrual period (LMP) was 10-SEP-2008 and her estimated date of delivery (EDD) by LMP was 17-JUN-2009, however was corrected to 08-JUN-2009 by early ultrasound. On 01-JUN-2009 (at 39 weeks gestation) the patient delivered a female neonate weighing 2690 gm/5lb and 15 ounces by C-section for non-reassuring fetal heart rate. The patient tested positive for group B strep and was treated with intravenous ((IV) antibiotics (name not provided) during labor. The baby's apgar scores were 7 at one minute, 8 at five minute and 9 at ten minute. It was reported that two days after birth, prior to discharge home, the baby was transferred to a Neonatal Intensive Care Unit (NICU) for a seizure like episode (not further specified). The physician did not have any record of the baby's exact or final diagnosis. He did note that the baby was not hospitalized for a long period of time and did not believe she was on any medication. The patient's last menstrual period was on 10-SEP-2008 and her estimated delivery date was on 08-JUN-2009 which was corrected by early ultrasound. Upon internal review, C-section for non reassuring fetal heart rate was considered to be an other important medical event. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: Apgar score, 06/01/09, 7, at the first minute; Apgar score, 06/01/09, 8, at 5 minute; Apgar score, 06/01/09, 9, at 10 minute; vaginal Streptococcus, positive

History:

Prex Illness: Pregnancy NOS (LMP=9/10/2008); Heavy smoker; Anaemia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352987-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Jul-2009	27-Jul-2009	0	03-Aug-2009	04-Aug-2009	--	WAES0907USA04871	04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1496X		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Grand mal convulsion, Loss of consciousness, Pallor, Syncope, Tremor

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female patient with a history of acne and no known drug allergies who on 27-JUL-2009 was vaccinated with a dose of GARDASIL (Lot: 661954/1496X). The patient did not receive any concomitant vaccines when the GARDASIL was administered to the patient. Concomitant therapy included tetracycline. There were no concomitant vaccines. On 27-JUL-2009, within five minutes of receiving GARDASIL, the patient became light headed, fainted and passed out while sitting in the waiting room with her mother. Her left arm had seizures movement and her right arm had slight seizure movement, the patient had a tonic-clonic seizure which lasted for 2 to 3 seconds. The patient abruptly awoke. The patient had not eaten prior to the physician's visit and prior to the GARDASIL vaccination. The nurse stated that the patient was given something to eat and drink after the incident had occurred. The patient was white and shaky for a while. On the same day, 27-JUL-2009, the patient recovered. The Registered nurse did not consider the patient's experience to be disabling or life-threatening. The registered nurse stated that she spoke with the patient's mother via a telephone call on 27-JUL-2009 and 28-JUL-2009. The patient's mother stated that the patient "was doing fine". Upon internal review tonic-clonic seizure was considered as other important medical event. Additional information has been requested.

Other Meds: tetracycline

Lab Data: None

History: Acne

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352988-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-May-2009	06-May-2009	0	03-Aug-2009	04-Aug-2009	FR	WAES0907USA04842	04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1647U	0	Unknown	Subcutaneously	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Fatigue, Incorrect route of drug administration, Injection site pain, Myalgia, Nausea, Paraesthesia

Symptom Text: Information has been received from Health Authority under reference: 2009-02868, concerning a 20 year old female patient with no pertinent medical history reported, who was vaccinated with 0.5ml first dose of GARDASIL (lot number: 1647U, batch number: NJ02280) via subcutaneous route (instead of intramuscular as recommended) on 06-MAY-2009. On the same day, she developed myalgias in the left upper limb associated with exquisite pain at the injection site. Two weeks after vaccination, the patient also developed paresthesias of the left hand. She received DAFALGAN and NSAID's as corrective treatment, without notable effect, the NEURONTIN which was stopped due to the appearance of fatigue and nauseas. There was no local reaction, i.e. no tumefaction, no redness, no pruritus. Two months after vaccination the myalgias and paresthesia still persisted without improvement. The Health Authorities considered the causal relationship with the vaccine as possible for the myalgias and paraesthesias and probable for the injection site pain. The reporter considered the patient's experiences to be disabling. Other business partner number is included E2009-06472. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **352994-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Jun-2009	17-Jun-2009	0	03-Aug-2009	04-Aug-2009	FR	WAES0907USA05093	04-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0773X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Loss of consciousness, Malaise, Muscle rigidity, Muscle spasms, Pallor, Vomiting

Symptom Text: Information has been received from a health authority under the reference number N200907-615. A 13 year old female patient received the first dose of GARDASIL (Lot number 0773X, Batch number NJ46700) intramuscular route on 17-JUN-2009. On the same day, she experienced general lipothymia associated with loss of consciousness, body rigidity indicating muscle spasms, severe pallor, hyperhidrosis and food vomiting. She recovered after approximately one and a half hour. Previous adverse reactions to any drug were unknown. The adverse events were considered to be an other important medical events. Other business partner numbers included: E2009-06798. No further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Adverse drug reaction

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353002-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-Mar-2009	23-Mar-2009	0	03-Aug-2009	10-Aug-2009	NJ		10-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: rash on face

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **353007-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Aug-2009	03-Aug-2009	0	03-Aug-2009	10-Aug-2009	IN		10-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB342 EB	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0642 X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U 2842 AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF 484 CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Heart rate normal, Nausea, Oxygen saturation normal, Syncope

Symptom Text: Syncope occurred 5 minutes after immunizations. C/O nausea, dizziness. B/P 138/60. Pulse 88. Oxygen saturation 96% room air.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353009-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Aug-2009	03-Aug-2009	0	03-Aug-2009	10-Aug-2009	IN		10-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0652 X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U 2842 AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	UF 484 CA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0471 Y	1	Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB 342 EB	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Heart rate normal, Nausea, Oxygen saturation normal, Pallor, Syncope

Symptom Text: Syncopal episode occurred 2 minutes after immunization. Assited to supine position with legs elevated. B/P 84/60. HR 64. Oxygen saturation 98%. Cool cloth to forehead & neck. Lips pale, skin moist. C/O nausea & dizziness. Recovered after 10 minutes. Denied further symptoms.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **353026-1 (S)** **Related reports:** 353026-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jan-2009	11-Mar-2009	68	04-Aug-2009	06-Aug-2009	WA		08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal discomfort, Activities of daily living impaired, Alopecia, Anaemia, Asthenia, Autoimmune disorder, Blood product transfusion, Contusion, Cough, Dizziness, Ear pain, Evans syndrome, Haemolytic anaemia, Headache, Hyperhidrosis, Idiopathic thrombocytopenic purpura, Musculoskeletal stiffness, Neutropenia, Oral contraception, Pallor, Palpitations, Petechiae, Platelet count decreased, Poor quality sleep, Pruritus, Pyrexia, Red blood cell count decreased, Tanning, Thrombocytopenia, Urticaria, Vaginal haemorrhage, Viral infection, Vision blurred, Wheezing, White blood cell count decreased

Symptom Text: Was doing fine after first after first shot, received 2nd series and next day went to dr. from school complaining of blurred vision, sick to stomach, and bad headache, fever and heart palpitations. Felt like was going to pass out. Went to dr. had tests and was in bed for 3 days. Blood tests came back low.. White, red and platelets.. Told 2 wait and be tested again in a few weeks. When tested again was sent to hospital and then diagnosed with ITP Syndrome and given medication.. Did not work, so then was hospitalized because blood was so low at serious risk for a stroke, was given another dose of globin and spent night at hospital.. A few weeks later, took blood tests again everything was still low, was put on highest dosage of Prednisone 4 3 weeks.. Blood levels raised and stabilized 4 a few weeks.. Latest has been diagnosed with ITP/Evans Syndrome and told would probably turn into Lupus, will have to visit hospital on a regular basis to be monitored.. A permanant disease, Rheumatologist and blood disorder doctors from 2 major hospitals agree this illnes was created by the Gardasil Vaccine and written in their reports. 8/10/09 PCP medical records received DOS 1/2/09 to 3/18/09. Assessment: Low platelet count. Hives/urticaria thighs and lower legs, itching after tanning session. Has started oral contraceptives. Heart palpitations, nausea, feverish. Headache, ears hurt, lightheaded. Looks pale. Excused from PE. 8/10/09 Hospital records and Oncology/Hematology consult, Rheumatology Consult, DOS 4/9/09 to 4/27/09. Assessment: Thrombocytopenia, anemia, neuropenia, positive lupus anticoagulant, elevated PT/PTT. Patient presents with thrombocytopenia, anemia, excessive vaginal bleeding. Had bad 'virus' with fevers, cough, headache, poor sleeping and sweating. Missed school. IVIG therapy. Hair is falling out. Energy levels decreased, pale, diffuse bruises, petechia over lower legs. Tightness in neck. Wheezing. 8/10/09 Hematology consult - second opinion, Rheumatology report DOS 4/21/09 to 5/19/09. Assessm

Other Meds: None

Lab Data: ITP/Evans Syndrome... Will eventually turn into Lupus. LABS and DIAGNOSTICS. 1/2/09 to 3/18/09: Platelets 63 (L). 4/9/09 to 4/27/09: CBC - RBC 3.27 X10'3 (L) Hemoglobin 10.2 g/dl (L) Hematocrit 30.3% (L) Platelets <5 X10'3 (L) Myeloc

History: allergies to penicillin. 'Easy bruiser''. Penicillin allergy. 'Ear tubes', dental extractions.

Prex Illness: No

Prex Vax Illns:

Vaers Id: **353026-2 (S)** **Related reports:** 353026-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jan-2009	11-Mar-2009	68	05-Oct-2009	06-Oct-2009	--	WAES0909USA01656	06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal discomfort, Activated partial thromboplastin time prolonged, Activities of daily living impaired, Alopecia, Anaemia, Antiphospholipid antibodies positive, Asthenia, Blood disorder, Blood product transfusion, Contusion, Cough, Dizziness, Ear pain, Evans syndrome, Headache, Hyperhidrosis, Idiopathic thrombocytopenic purpura, Muscle tightness, Nausea, Neutropenia, Oral contraception, Pallor, Palpitations, Petechiae, Platelet count decreased, Prothrombin time prolonged, Pruritus, Pyrexia, Sleep disorder, Urticaria, Vaginal haemorrhage, Viral infection, Vision blurred, Wheezing, White blood cell count decreased

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 17 year old female with penicillin allergy, easy bruiser, "ear tubes" and a history of dental extractions was vaccinated with a first dose of GARDASIL (lot# 661703/0651X) IM in the left arm on 02-Jan-2009. No other medications. The patient was doing fine after the first shot. She received the second series and on the next day, 11-MAR-2009, went to doctor from school complaining of blurred vision, sick to stomach and bad headache, fever and heart palpitations. Felt like was going to pass out. She went to doctor and had tests and was in bed for 3 days. Blood tests came back low, white, red and platelets. She was told to wait and be tested again in a few weeks. When tested again, she was sent to hospital and then diagnosed with ITP syndrome and was given medications. Did not work, so then was hospitalized because blood was so low, at serious risk for a stroke. She was given another dose of globin and spent night in hospital. A few weeks later, she took blood tests again, everything was still low, and she was put on highest dosage of prednisone for 3 weeks, blood levels raised and stabilized for a few weeks. Latest has been diagnosed with ITP/Evans Syndrome and she was told would probably turn into lupus. She would have to visit hospital on a regular basis to be monitored. A permanent disease, rheumatologist and blood disorder doctor from 2 major hospitals agree this illness was created by GARDASIL and written in their reports. On 10-AUG-2009, PCP medical records received 02-Jan-2009 to 18-MAR-2009. Assessment: low platelet count, hives/urticaria thighs and lower legs, itching after tanning session. She had started oral contraceptives. Heart palpitations, nausea, feverish, headache, ears hurt, lightheaded, looks pale. She was excused from PE. On 10-AUG-2009, hospital records and oncology/haematology consult and rheumatology consult from 09-APR-2009, to 27-APR-2009 was received. Assess

Other Meds: None

Lab Data: Platelet count, ?/?/09, 63, 02-JAN-2009 to 18-MAR-2009; Red blood cell count, 04/??/09, 3.27*, 09-Apr-2009 to 27-APR-2009; Hemoglobin, 04/??/09, 10.2 g/dl, 09-Apr-2009 to 27-APR-2009; Hematocrit, 04/??/09, 30.3%, 09-Apr-2009 to 27-APR-2009;

History: Tooth extraction

Prex Illness: Penicillin allergy; Increased tendency to bruise

Prex Vax Illns:

Vaers Id: **353032-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jul-2009	23-Jul-2009	0	03-Aug-2009	13-Aug-2009	MO		09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	00874	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Face injury, Fall, Immediate post-injection reaction, Syncope

Symptom Text: Pt fainted very shortly after injection. Fell forward off table & broke her nose.

Other Meds:

Lab Data: X-ray of nasal bones

History: None known

Prex Illness: None known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353034-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Jul-2009	28-Jul-2009	0	03-Aug-2009	13-Aug-2009	WA		14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2669AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling hot, Nausea, Pallor

Symptom Text: Approx. 2 min after injections, became pale, nauseated, dizzy, + felt "hot". Vital signs stable. After 15" up to chair. Denied nausea or dizziness, color improved, skin warm & dry.

Other Meds:

Lab Data:

History: None

Prex Illness: None known

Prex Vax Illns:

Vaers Id: **353037-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Oct-2008	01-Jan-2009	79	03-Aug-2009	13-Aug-2009	TN		14-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1978U	0	Right arm	Intramuscular	
TD	GLAXOSMITHKLINE BIOLOGICALS	AC32BD19AA		Right arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB238AA		Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Activities of daily living impaired, Alopecia, Anorexia, Arthralgia, Asthenia, Burning sensation, Chest pain, Crying, Fatigue, Gait disturbance, Hypotonia, Lethargy, Muscular weakness, Musculoskeletal pain, Nausea, Nuclear magnetic resonance imaging normal, Pain, Pyrexia, Sleep disorder

Symptom Text: 7/22 Woke up during the night from a really bad sharp pain in chest. She barely touched it and the sharp pain would return same with shoulders. 7/22 Tired and sore from therapy. I want to give a little history on this patient. She was a cheerleader, majorette, and was in a weight lifting class. She was very active and athletic. I didn't have enough room on the VAERS for this so I am attaching this sheet for a timeline. 10/14/08 1st GARDASIL. 12/29/08 2nd GARDASIL. 01/09 School reported she was generally weak and fatigued to the point of needing to leave school. 02/09 She started with having leg weakness and would like wrap her ankles for performances and practices (no injuries) just weakness. 03/09 The actual leg and joint pain started. She was refusing to do stunts in cheerleading because it hurt so bad. She is the "flyer" because of her small size and she said it hurt too bad to climb up and to be caught. 04/09 Not a lot of activity during the month with cheering or anything, but she had to be picked up from school several times because the exertion just from walking from class to class made her so tired she had to go to bed. 05/09 The week of the 11th she had to be picked up from school because of lethargy just from decorating for the prom. The week of the 18th she started with a limp more prominent in the R leg. Substantially increased pain in the joints and "shooting, needle-stick pains in the shin area". The following week she started losing muscle control and could not walk or stand without help and started using crutches. She complained of "burning, stabbing, achy" pains in many different areas. Her hips, arms, and leg muscles had significantly increased pain. Because of the severity of the pain and loss of muscle control in her legs, she was taken to ER on May 31. She was sent to hospital at that time. 06/09 She went to an Orthopedic Dr and they said it was neurological. She started seeing a Neurologist, she was doing MRI's and further testing and they couldn't find anything so they are sending her to a

Other Meds:

Lab Data: Please see attached

History: heart murmur

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353060-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-Jul-2009	28-Jul-2009	1	03-Aug-2009	14-Aug-2009	MI		14-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB286AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2872A9	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0548X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discomfort, Injection site erythema, Injection site urticaria, Injection site warmth

Symptom Text: L arm has two welt sites one aprox. 4 cm & improving 2nd site 6 cm & warm to touch & red. with discomfort lasting 2 days - improving with MOTRIN. Continue with MOTRIN & ice if worsens outline area for monitoring and return to physician.

Other Meds:

Lab Data:

History: Allergy to Sulfa

Prex Illness:

Prex Vax Illns:

Vaers Id: **353069-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Jul-2009	01-Jan-2009	-194	03-Aug-2009	14-Aug-2009	TN		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Abdominal discomfort, Activities of daily living impaired, Alopecia, Anorexia, Arthralgia, Burning sensation, Chest pain, Crying, Dysstasia, Fatigue, Gait disturbance, Hypokinesia, Hypotonia, Induration, Lethargy, Muscular weakness, Musculoskeletal pain, Nausea, Nuclear magnetic resonance imaging, Pain, Pain in extremity, Pyrexia, Walking aid user

Symptom Text: I want to give a little history on this patient. She was a cheerleader, majorette, and was in a weight lifting class. She was very active and athletic. I didn't have enough room on the VAERS for this so I am attaching this sheet for a timeline. 10/14/08 1st GARDASIL. 12/29/08 2nd GARDASIL. 01/09 School reported she was generally weak and fatigued to the point of needing to leave school. 02/09 She started with having leg weakness and would like wrap her ankles for performances and practices (no injuries) just weakness. 03/09 The actual leg and joint pain started. She was refusing to do stunts in cheerleading because it hurt so bad. She is the "flyer" because of her small size and she said it hurt too bad to climb up and to be caught. 04/09 Not a lot of activity during the month with cheering or anything, but she had to be picked up from school several times because the exertion just from walking from class to class made her so tired she had to go to bed. 05/09 The week of the 11th she had to be picked up from school because of lethargy just from decorating for the prom. The week of the 18th she started with a limp more prominent in the R leg. Substantially increased pain in the joints and "shooting, needle-stick pains in the shin area". The following week she started losing muscle control and could not walk or stand without help and started using crutches. She complained of "burning, stabbing, achy" pains in many different areas. Her hips, arms, and leg muscles had significantly increased pain. Because of the severity of the pain and loss of muscle control in her legs, she was taken to ER on May 31, She was sent to hospital at that time. 06/09 She went to an Orthopedic Dr and they said it was neurological. She started seeing a Neurologist, she was doing MRI's and further testing and they couldn't find anything so they are sending her to another Neurologist (08/14/09). She also started losing clumps of hair, not sure of the actual date but it started in June and is worsening some throughout the month of July with a

Other Meds:

Lab Data: see attached

History: heart murmur

Prex Illness: none

Prex Vax Illns: weak, fatigued~HPV (Gardasil)~2~15~Patient

Vaers Id: **353070-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Dec-2008	08-Jan-2009	10	03-Aug-2009	14-Aug-2009	TN		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Abdominal pain upper, Activities of daily living impaired, Adverse drug reaction, Alopecia, Arthralgia, Asthenia, Chest pain, Cushingoid, Electrocardiogram abnormal, Fatigue, Gait disturbance, Headache, Lethargy, Lymphadenopathy, Muscular weakness, Musculoskeletal pain, Myalgia, Nausea, Oedema peripheral, Pain, Pain in extremity, Pain in jaw, Paraesthesia, Pyrexia, Steroid therapy, Swelling face, Throat tightness, Walking aid user, Weight increased, Wheelchair user

Symptom Text: 1/08 - school reported she was very weak - 03/09 leg weakness/tired 03/09 pain started. Please see attached. Patient continuity codes to 353037 and 353069. VAERS report received with MR and notes from PCP. Pt developed weakness and fatigue shortly after 2nd HPV vax on 12/2908. ADLs greatly reduced due to lethargy and fatigue. Developed joint pain and pins & needles shin pain and loss of muscle control in 5/2009 Walked with a limp 2' to pain. See ER notes. Neuro consults with no specific dx. Referred to another neuro and will be seen 8/2009. In June 2009 developed hair loss. Following 3rd HPV shot 7/14/09 developed sharp chest and shoulder pain, fever, nausea and stomach pain, worsening pain in fingers, thrumb, wrist, elbow and arm. 8/28/09 ER records rec'd for DOS 5/31/09 with DX: Acute lower extremity sense of weakness. Acute LE paresthesias. Presented with c/o joint pain and weakness in legs since 5/18/09. Unable to walk. sharp pains in shins and thighs. Occ feels like airway is closing. PE (+) stiff-legged, wide-based gait. Referral notes EKG abnormality, lower extremity strength 3/5, upper extremity 4/5. Referral made for outpt PT. 10/8/09 Neurology consult, rheumatology consult, pediatric pain service records received, service dates 8/14/09 to 10/1/09 Assessment: Diffuse musculoskeletal pain, amplified pain. Abnormal ESR. Chronic steroid use. Patient presents for evaluation of diffuse pain. Intermittent activity-dependent fatigue and generalized weakness, Aching pain entire body. Transient swelling of face and hands. Jaw aches after chewing. Activities limited. Uses cane or wheelchair for walking more than a few steps. Occipital headaches. "Crouched" gait. Brief cervical lymphadenopathy. On corticosteroids - Cushingoid face and 30 lb undesired weight gain, sleep disturbances. Muscle tenderness and tender points. Antalgic gait. Episode of severe chest pain.

Other Meds:

Lab Data: Labs: CSF WNL. ESR 38. EKG WNL. 10/8/09 service dates 8/14/09 to 10/1/09. LABS and DIAGNOSTICS: CDC - WBC 27.7 thou/uL RDW 14.7% (H) Neut 67.5% (H) Neut 17.36 thou/uL (H) Lymph 6.38 thou/uL (H) Baso 0.00 thou/uL (L). EBCAgG (+) EBAgAB (

History: Heart murmur PMH: low K+. 10/8/09 service dates 8/14/09 to 10/1/09. Presyncope, low serum potassium. Frenulectomy.

Prex Illness: None

Prex Vax Illns: See attached~ ()~~0.00~Patient

Vaers Id: 353079-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	12-Jun-2008	15-Aug-2008	64	04-Aug-2009	05-Aug-2009	SC	WAES0907USA03319	05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Haemorrhage, Oedema, Pre-eclampsia, Pregnancy induced hypertension, Vaginal haemorrhage

Symptom Text: Initial and follow-up information has been received from a nurse, for GARDASIL, a Pregnancy Registry product, concerning a 23 year old female who on 07-JAN-2008 was vaccinated with the first dose of GARDASIL (lot# 659439/1267U, IM, 0.5ml). On 12-JUN-2008 the patient received the second dose of GARDASIL (lot# 660391/0063X, IM, 0.5ml). Concomitant therapy included LEXAPRO. After the second dose the patient was pregnant and her last menstrual period (LMP) date was at 15-AUG-2008. On 26-SEP-2008 the patient experienced pre-eclampsia and spotting/bleeding; intervention was observation. Lab diagnostics studies included ultrasounds-normal, fetal echocardiogram at 37 weeks-normal, urine protein test-normal. On 08-MAY-2009 the patient was admitted for delivery at hospital. The patient did experience "pregnancy induced hypertension" at delivery, but hospitalization was not prolonged due to this event. The baby boy (8lb 4oz) born with no complications. The patient was seen in the office on 21-JUL-2009, blood pressure (B/P) was normal (120/72) at that visit. The patient had not yet received the 3rd dose of GARDASIL. At the report time the patient's status was unknown. In follow-up, a nurse reported the 23 year old white female had no previous pregnancies. Her concurrent medical conditions were reported as "stable". Other medication used during her pregnancy included precare vitamin (the date of use was reported as "25-SEP-2009"). Her pregnancy was complicated by pregnancy-induced hypertension and she developed edema. Subsequently, on 09-MAY-2009, the patient delivered a normal male baby by C-section delivery weighing 8 pounds 4 ounces. The baby had no congenital anomalies or any other complications or abnormalities. No further information is available.

Other Meds: LEXAPRO

Lab Data: Ultrasound, normal; Echocardiography, 05/01?/08, fetal normal; Blood pressure, 05/08/09, pregnancy induced hypertension; Blood pressure, 07/21/09, normal, 120/70; Urine protein, normal

History:

Prex Illness: Pregnancy NOS (LMP = 8/15/2008)

Prex Vax Illns:

Vaers Id: 353080-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	12-Nov-2008	15-Dec-2008	33	04-Aug-2009	05-Aug-2009	NJ	WAES0907USA04234	18-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	02926AA		Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Back pain, Cerebellar syndrome, Chest pain, Epidural anaesthesia, Hyperreflexia, Insomnia, Multiple sclerosis, Muscle twitching, Muscular weakness, Neck pain, Oedema peripheral, Pain in extremity, Paraesthesia, Peripheral coldness, Skin discolouration, Tongue paralysis

Symptom Text: Information has been received from a physician concerning a female who in January 2009, was vaccinated IM with the second 0.5ml dose of GARDASIL (lot# not reported). The patient exhibited "multiple sclerosis (MS)-like symptoms". The date of onset of the symptoms was unknown. The patient was hospitalized overnight at hospital for testing to rule-out multiple sclerosis. The physician relayed that unspecified test results were "non-specific". The dates of hospitalization were unknown. The physician did not provide details of the specific symptoms experienced by the patient but added that "the symptoms are improving." Follow up information was received via telephone call from the patient's mother who worked in the doctor's office and was not a Health Professional provided the patient's full name and birth date. It was reported that the patient was 23 year old and had received 2 doses of GARDASIL. The patient received the first dose of GARDASIL from her gynecologist (GYN) physician (date, dose and lot number unknown to reporter). The patient received the second dose of GARDASIL on 12-NOV-2008 (lot# 659184/0843X) (previously reported as January 2009). The patient began having the following symptoms in the middle of December 2008; "Swelling in her arm, twitches, constant back pain, could not walk at times". The patient was hospitalized of over night, early in 2009 to rule out (R/O) multiple sclerosis (MS) (hospital name and hospitalization dates not reported). The patient's mother stated that the patient could walk and was improving. Follow up information was received via telephone call from a person from the patient's gynecologist's office who provided the doctor's address and reported that the patient received the first dose of GARDASIL on 05-MAY-2008 (expiration date 14-JUN-2009). Additional information has been requested. 8/7/09 Medical records received DOS 11/12/08 to 7/28/09. C/O heartburn, rosacea, joint stiffness. Second dose of Gardasil administered. Post vaccination patient presents with back pain, insomn

Other Meds: Unknown. 8/7/09 Medical records received DOS 11/12/08 to 7/28/09. 'B12 pills'

Lab Data: Unknown. 8/7/09 Medical records received DOS 11/12/08 to 7/28/09. LABS and DIAGNOSTICS: Mantoux. 8/10/09 Hospital records received DOS 12/26/09 to 1/24/09. LABS and DIAGNOSTICS: MRI Cervical Spine - Right sided predominant disc bulge at

History: Unknown. 8/10/09 Hospital records received DOS 12/26/09 to 1/24/09. B12 deficiency, bipolar disease, asthma. Septoplasty. Alcohol, tobacco use. Fibromyalgia. Sulfa allergy.

Prex Illness: 8/7/09 Medical records received DOS 11/12/08 to 7/28/09. C/O heartburn, rosacea, joint stiffness.

Prex Vax Illns:

Vaers Id: 353081-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-May-2008	21-May-2008	0	04-Aug-2009	05-Aug-2009	--	WAES0907USA04345	05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received from a physician and a certified medical assistant, for GARDASIL, a Pregnancy Registry Product, concerning her 17 year old niece no pertinent medical history and no known allergies who on 14-NOV-2007 was vaccinated (injection) with a first dose of GARDASIL (lot# (lot# 659437/1266U) a second dose on 16-JAN-2008 (lot# 659439/1267U), and a third dose was administered on 21-MAY-2008 (lot# 660389/1968U). There was no concomitant medication. In June 2008 the patient found out she was pregnant. The patient then had her baby in March 2009 and the baby was born with brain swelling. The baby then had surgery (name of hospital, address and phone number unspecified) to have the fluid around the brain drained and once the fluid was drained the physician noticed that the baby's brain was not fully developed in the frontal cortex. The certified medical assistant reported that the patient and baby were under care with the patient's Obstetrician/Gynecologist (OBGYN). The patient's last menstrual period (LMP) was reported as "around June 2008". The patient was determined to be pregnant in December 2008 when she was 6 months gestation. The patient delivered a male infant on 23-MAR-2009. The infant was diagnosed with hydranencephaly at birth (also reported by the physician as 2 months after birth). Unspecified medical attention was sought. At the time of the report, the patient had not recovered. The physician reported that she was unsure about the patient's prenatal care. Follow up information was received on 28-JUL-2009 via telephone call from a registered nurse who reported that concomitant therapy included MENACTRA (lot# U2538AA) and influenza virus vaccine (unspecified) (lot# U2475KA). The nurse confirmed that there was no pertinent medical history and no known drug allergies (NKDA) and the only therapy taken by the patient was pm naproxen for menses. The nurse was not certain, but believed it was the patient's first pregnancy. LMP date and length of gestation were not available from the nurse's of

Other Meds:

Lab Data: head computed axial, 06/18/09, baby: "vastly abnormal"; ultrasound, 06/18/09, baby: "vastly abnormal"

History:

Prex Illness: Pregnancy NOS (LMP = 6/1/2008)

Prex Vax Illns:

Vaers Id: 353082-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	06-Nov-2008	06-Nov-2008	0	04-Aug-2009	05-Aug-2009	--	WAES0907USA04362	05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dehydration, Stool analysis, Urine analysis

Symptom Text: Information has been received from a 23 year old female patient with no pertinent medical history and sulfonamide allergy who on 06-NOV-2008 was vaccinated with the first dose of GARDASIL (lot number not reported). On 03-FEB-2009 the patient was vaccinated with the second dose of GARDASIL (lot number not reported). Concomitant therapy included NEXIUM. On 06-NOV-2008 the patient was submitted to hospital because she was dehydrated after a fight. A urinalysis was performed and stool sample was collected for dehydration (results not provided). At the time of the report, the outcome of the patient was unknown. Additional information has been requested.

Other Meds: NEXIUM

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: 353083-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-May-2009	16-Jul-2009	65	04-Aug-2009	05-Aug-2009	FR	WAES0907USA04417	05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1316U	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Condition aggravated, Injection site pain, Streptococcal infection

Symptom Text: Case received from a health care professional on 21-JUL-2009 and additional information on 24-JUL-2009. It was reported by a physician that a 15 year old female patient was vaccinated with a second dose of GARDASIL (Lot: 1316U, Batch: NH24910) IM into the left upper arm on 14-JUL-2009. On 16-JUL-2009 the patient developed pain at the injection site and pain in elbow of the vaccinated arm (left). On 18-JUL-2009 severe pain in both knees started. Treatment with Diclofenacnatrium showed no improvement. Pain increased during the night. Therefore the patient was hospitalized on 20-JUL-2009. A blood sample was taken and showed increase values for serum C-reactive protein test (CRP), leukocytes and erythrocyte sedimentation rate. Further diagnostics were carried out at the time of reporting. The result of the laboratory values showed an increased antistreptolysin titer. The diagnosis of post streptococcal infection was established. Under treatment with naproxen the symptoms were resolving. Further diagnostic investigations with regard to rheumatic diseases were intended. The patient developed pain in elbow of vaccinated arm (left) after received the first dose of GARDASIL (Lot: 1115U, Batch: NH33310), on 12-MAY-2009 and recovered completely within an unspecified time. Other business partner numbers include E2009-06171.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 20?Jul09, showed an increased antistreptolysin titer; WBC count, 20?Jul09, increased values; serum C-reactive protein, 20?Jul09, increased values; erythrocyte sedimentation rate, 20?Jul09, increased values

History: Pain in elbow

Prex Illness:

Prex Vax Illns:

Vaers Id: 353084-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	09-Aug-2008	09-Mar-2009	212	04-Aug-2009	05-Aug-2009	FR	WAES0907USA04753	05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1282U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cervical dysplasia, Cervicitis, Papilloma viral infection

Symptom Text: Case received from a general practitioner on 03-JUL-2009 who transmitted through a sales representative. The physician was called: A 19-year-old female patient under oral contraceptive received the three doses of GARDASIL (lot# and batch # not reported) respectively on 01-FEB-2008, 21-APR-2008 and 09-AUG-2008. On 09-FEB-2009, an abnormal pap smear revealed a malpighian lesion CIN2. A colposcopy was performed which showed an iodo-heterogeneous lesion at the level of the posterior lip of the cervix uteri. A biopsy showed a dysplasia of the cervix uteri, associated to human papillomavirus lesion. There was no information concerning the human papillomavirus typing. The patient was treated with miniconization. To be noted that the reporter had doubts about the patient's date of first sexual intercourse (after or before completing GARDASIL vaccination schedule; 3 doses), because the patient was already under oral contraceptive when she received GARDASIL. Information received through PV form on 28-JUL-2009 and Anatomy and Pathological Cytology reports: Case upgrade to serious as the patient was hospitalized. The patient had received the first dose of GARDASIL via intramuscular route in the left deltoid respectively on 01-FEB-2008 (lot # 0484U, batch # NG29160), 21-APR-2008 (lot # 0588U, batch # NG34100) and 09-AUG-2008 (lot # 1282U, batch # NH47590). On 09-MAR-2009 (instead of 09-FEB-2009 as previously reported), she experienced a dysplasia of the cervix uteri CIN2. She was treated with miniconization on 06-MAY-2009. High grade (CIN2) malpighian intraepithelial lesion associated to human papillomavirus lesion (without typing) was diagnosed. The reporter mentioned that the patient was hospitalized (no other precision). Anatomy and Pathological Cytology report on 09-MAR-2009: Cervical smear was performed. The report concluded to a cytological aspect in favor of high grade (CIN2) malpighian intraepithelial lesion. Biopsies under control colcoscopic were recommended. Anatomy and pathological cytology report on 12-MAY-2009;

Other Meds: Hormonal contraceptives (unspecified)

Lab Data: Colposcopy, 09Mar09, showed an iodo-heterogeneous lesion at the level of the level of the posterior lip of the cervix ute; Cervical smear, 09Mar09, cytological aspect in favor of high grade (CIN2) malpighian intraepithelial lesion; Diagnost

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353085-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	26-Sep-2007	26-Sep-2007	0	04-Aug-2009	05-Aug-2009	FR	WAES0907USA05052	05-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Myalgia, No reaction on previous exposure to drug, Photophobia, Pyrexia

Symptom Text: Information has been received from a health authority concerning a female of unknown age. The patient had received the first two doses of GARDASIL on 12-FEB-2007 and an unspecified date with no adverse effect. The patient received the third dose of GARDASIL (batch number not reported, intramuscularly), on 26-SEP-2007. On 26-SEP-2007, the same day as vaccination, the patient experienced a high temperature (39 C) with headache, muscle pain and mild photophobia. The patient recovered after 8-10 hours on 27-SEP-2007. The patient received all three doses of the vaccine and the reaction only occurred after the third dose. There was no confirmation of diagnosis and there was no other reason for the high fever which resolved so quickly. The reporter considered the events to be medically significant. Other business partner's numbers included: E2009-06802 and ADR 20185610. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: body temp, 39 C

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353096-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Jul-2009	16-Jul-2009	1	04-Aug-2009	14-Aug-2009	IL		14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB342EB	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1531X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain, Pruritus

Symptom Text: 7-8" of redness, itchy and painful for 1 wk.

Other Meds:

Lab Data:

History: Tinea pedis; Acne; Chronic knee pain; Overweight

Prex Illness: None

Prex Vax Illns: Same as above~HPV (Gardasil)~1~14~Sibling

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353101-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Jul-2009	24-Jul-2009	4	04-Aug-2009	14-Aug-2009	LA		14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oropharyngeal blistering, Rash

Symptom Text: Rash to hands and feet (blisters) sores in mouth. Treated with ZYRTEC and BENADRYL mouth wash mixture.

Other Meds: none

Lab Data:

History: none

Prex Illness:

Prex Vax Illns:

Vaers Id: **353102-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Jul-2009	28-Jul-2009	1	04-Aug-2009	16-Aug-2009	OK		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: On 27 July 09 child received 3rd HPV vaccine in left arm. On 28 July 09 a lump was seen over injection area. Was seen on 29 July for a check up again on 31 July 09 the lump was slightly smaller. No treatment received or required.

Other Meds: ZYRTEC; XOPENEX; BENZACLIN

Lab Data:

History: Allergy to cats.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353105-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jul-2009	25-Jul-2009	1	04-Aug-2009	14-Aug-2009	NC		14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Dizziness, Dyspnoea, Headache, Hyperhidrosis, Musculoskeletal stiffness

Symptom Text: Neck stiffness, Headache, Extreme sweating, chest pain, diff. Breathing, and feeling faint.

Other Meds: DEPO-PROVERA

Lab Data: None

History: UTI; Migraines

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353106-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Jul-2009	27-Jul-2009	3	04-Aug-2009	16-Aug-2009	LA		17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cyanosis, Erythema, Injected limb mobility decreased, Oedema peripheral, Pain in extremity, Skin warm

Symptom Text: 7-27-09 1:00 PM Mom called to report daughter's (R) arm was red, swollen and real sore. She also couldn't pick up her arm very high. Mom called back at 4: 00 PM. Her (R) arm was hot to touch and her (R) arm from elbow to hands were turning purplish blue - went to ER.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **353111-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Jul-2009	16-Jul-2009	1	04-Aug-2009	14-Aug-2009	IL		14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1531X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain, Pruritus

Symptom Text: 2-3" circular redness-itchy and painful to touch for 1 week.

Other Meds: Benzyl peroxide 10% Gel

Lab Data:

History: acne; overweight

Prex Illness: none

Prex Vax Illns: same as above~HPV (Gardasil)~1~16~Sibling

Vaers Id: 353112-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Jan-2009	26-Jan-2009	0	04-Aug-2009	16-Aug-2009	--		17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB185BO	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	WH29070	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Rash maculo-papular, Swelling face

Symptom Text: Night of immunization mac/pap rash of face and neck with some swelling of face with erythema and itching. Resolved in 2 weeks time with Zyrtec. No vesicles. Brother received varicella at same time.

Other Meds: None

Lab Data: None

History: Allergic to pollen

Prex Illness: None

Prex Vax Illns: Rash forehead~Varicella (no brand name)~2~9~Sibling|Rash forehead~Hep A (no brand name)~1~9~Sibling

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353113-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-May-2009	Unknown		04-Aug-2009	16-Aug-2009	MI		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Vaccine administered to pregnant female approximated 3 weeks gestation. Report LMP 5/5/09, denied sexual activity. EDC 2/4/10.

Other Meds: None

Lab Data: Pregnancy verified by ultrasound 7/14/09.

History: Pregnancy unknown at time of administration.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353117-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Aug-2009	03-Aug-2009	0	04-Aug-2009	10-Aug-2009	OH		10-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2937BA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1978U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Nausea, Vomiting

Symptom Text: Childs mother called at 9:30am this morning reporting that the child had nausea and vomiting during the night. She stated child vomited once during the night and once early this morning. Reports stomach "pain". Mother denied child had a fever. Mother stated she had not treated the child with any medications.

Other Meds: unknown

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **353120-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Aug-2009	04-Aug-2009	0	04-Aug-2009	14-Aug-2009	IN		14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652 X	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0471 Y	2	Right arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB 342 EB	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U 2842 AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Syncopal episode 2 minutes after immunizations. Fell to floor. B/P 98/64; Pulse 83; Oxygen sat 98%. Legs elevated. Recovered without incident; denies pain.

Other Meds:

Lab Data:

History: nONE

Prex Illness: nONE

Prex Vax Illns:

Vaers Id: 353124-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	31-Aug-2007	25-Oct-2007	55	04-Aug-2009	06-Aug-2009	FL		17-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Balance disorder, Cognitive disorder, Confusional state, Demyelination, Diplopia, Hypoaesthesia, Hypoaesthesia facial, Hypoaesthesia oral, Multiple sclerosis, Visual acuity reduced

Symptom Text: Approximately 1 month after receiving the second dose of the Gardasil vaccine (manufactured by Merck - I am unable to load that in the information section below), I began experiencing numbness in my right leg. The numbness was persistent and progressive - it began in the right leg, but soon spread to the left leg, as well as my face and tongue. I also experienced poor balance, poor vision, confusion, and overall weakness. I was admitted to the hospital 3 weeks later, and kept for one week while receiving intravenous corticosteroids as treatment. 8/24/09 consultant records 1/09-received for numbness of right leg below knee right face and tongue numbness between Oct 07 and Feb 08 when symptoms improved and then in March 08 recurrent symptoms. Developed diplopia, dizziness, cognitive impairment, abdominal problems and fatigue. Impression: MS. JC Virus DNA, QN RT-PCR <500. ```MR and DC summary received 01/27/10 for DOS 11/08/07-11/12/07. DX: central nervous system demyalinating disease, likely MS. Pt presented with progressive paresthesias and gait difficulties. Pt underwent MRI and CSF testing and it was abnormal. Tx: Solu-Medrol. Pt L extremities improved mobility and walking. Pt had notable diminished propriception in the R lower extremity and prominent heel strike walking, but they improved at discharge time. Pt to follow up with neurologist.

Other Meds:

Lab Data: A multitude of blood tests were done, along with MRIs, x-rays, and a lumbar puncture 8/24/09-records received-JC Virus DNA, QN RT-PCR <500. ```Lab and DX studies: MRI: abnormal with small subcortical lesions. CSF: no infection.

History: ```PMH and allergies: none.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **353143-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Jul-2009	31-Jul-2009	0	04-Aug-2009	17-Aug-2009	MI		17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Heart rate decreased, Loss of consciousness, Pallor, Syncope, Tremor

Symptom Text: Within 5 min of receiving HPV #3 in a semi-lying down position she started having some tremors and passed out. B/P at that time was 102/59 with a pulse of 49. She was pale around lips. She was more woozy then passed out. She was placed in flat supine position and given juice & crullers. She stayed supine for another 30 min. When she started to get up she fainted at that time. At that time her BP was 94/58, P = 40. She was observed over the next 30-35 min and her BP increased to 107/64 with P = 40. Color much better. She was observed over the next hour and a half with BP & P observed every 15 min. She was observed for 2 hrs since coming in with BP 112/68.

Other Meds: Tetracycline 500mg cap twice a day; PPD

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353149-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-Jul-2009	28-Jul-2009	0	04-Aug-2009	17-Aug-2009	AZ		17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0313Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives

Other Meds: None

Lab Data: Benedryl Given

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 353170-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	28-Apr-2008	05-Jun-2008	38	05-Aug-2009	06-Aug-2009	NJ	WAES0810USA04728	06-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse (R.N.), for the Pregnancy Registry for GARDASIL, concerning a 22 year old female who was intramuscularly vaccinated with the first and second 0.5 ml doses of GARDASIL (first lot #0151X, second lot #0250X) on 28-APR-2008 and 30-JUN-2008, respectively. The patient had 3 previous pregnancies and 2 elective terminations. Subsequently, the patient discovered that she was pregnant. Her LMP was 15-JUN-2008. On 03-SEP-2008, she had ultrasound and "the results were normal and she was 12 weeks gestation at that time". On 13-OCT-2008, she had serum alpha-fetoprotein test and the result was normal. No adverse effects reported. The patient sought medical attention via office visit. Additional information was received from a physician via Initial Pregnancy Questionnaire. The physician reported the patient had 3 previous pregnancies and 2 elective terminations. The patient's LMP was 15-JUN-2008 and estimated delivery date was 02-MAR-2009. The result of patient's serum alpha-fetoprotein test was normal on 13-OCT-2008. Follow up information was received via pregnancy questionnaire indicated that the patient delivered a normal male baby on 05-MAR-2009, 38-39 weeks from the patient's LMP, weighting 9.1, length 21 inches. There was no congenital anomalies, complication, infections or illnesses during pregnancy and no complication during labor/delivery. It was also noted that the patient took VITAFOL during this pregnancy. Follow up information was received which reported the patient with G3P0 on 05-MAR-2009 underwent C-section. The baby was well health. Upon internal review, the C-section was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 09/03/08, results were normal and 12 weeks gestation; serum alpha-fetoprotein, 10/13/08, normal

History:

Prex Illness: Pregnancy NOS (LMP = 6/15/2008)

Prex Vax Illns:

Vaers Id: 353171-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Feb-2009	01-Feb-2009	0	05-Aug-2009	06-Aug-2009	--	WAES0907USA05405	06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1496X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Faecal incontinence, Hypoaesthesia, Multiple sclerosis, Sensory disturbance, Urinary incontinence, Urticaria, Vertigo

Symptom Text: Information has been received from a consumer concerning his 25 year old god-daughter who, 4 or 5 months ago, in approximately February 2009, was vaccinated with her first dose of GARDASIL (route and site not reported). About a week later the patient experienced numbness on her lower body. When the patient sought medical attention, she underwent MRI and other various tests and the doctors diagnosed her with multiple sclerosis (MS). At the time of reporting the patient's multiple sclerosis persisted. Upon internal review, multiple sclerosis was considered to be an other important medical event. This is one of several reports received from the same source. Additional information has been requested. 10/2/09 Medical records received for Neurologist consultation for dates of service 6/30/09 and 7/15/09. DX: MS. Presenting symptoms: initial episode of left arm and leg numbness and hives 1 day after gardasil vaccination. Later 5/09 episode numbness from navel down, abnormal sensation in both legs, bowel and bladder incontinence, later resolved. Vertigo.

Other Meds: None

Lab Data: magnetic resonance; diagnostic laboratory, various tests for MS 10/2/09 Medical records received for Neurologist consultation for dates of service 6/30/09 and 7/15/09 Diagnostics/Lab: MRI abnormal- 3 areas of demyelinization. MRI cervical

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353172-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		05-Aug-2009	06-Aug-2009	--	WAES0908USA00003	06-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Multiple sclerosis, Paraesthesia

Symptom Text: Information has been received from a consumer concerning one of her co workers who was vaccinated with a dose of GARDASIL (date, route and site not reported). Subsequently the patient started to experienced numbness and tingling in her right arm, hand and her feet. A few months later the patient was diagnosed with multiple sclerosis (MS). The outcome of the patient's multiple sclerosis was not reported. Upon internal review, multiple sclerosis was considered to be an other important medical event. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **353189-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Jul-2009	28-Jul-2009	0	05-Aug-2009	17-Aug-2009	ND	ND-09-07	18-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0206Y	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041CA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2845AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Dyspnoea, Skin lesion, Urticaria

Symptom Text: SHORTNESS OF BREATH, CHEST PRESSURE, HIVES, AND SORES

Other Meds: CLEOCIN-T; RETIN-A CREAM; BENZOYL PEROXIDE WASH

Lab Data: NONE

History: NON

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **353200-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Jul-2009	31-Jul-2009	0	05-Aug-2009	17-Aug-2009	OH		18-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0262Y	0	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2727AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Fatigue, Malaise, Nodule, Tenderness

Symptom Text: Mother brought child to HD office 8/3/09 PM to report that child's arm became tender, with redness over deltoid spreading to just aboeve the elbow PM 7/31/09. c/o being tired and "just not feeling well" continuing today. there had been a "knot" in her arm, but it is now gone. Did not check for fever. Gave Ibuprofen, used cool compress off and on for 2 days.

Other Meds: NONE

Lab Data: None

History: NONE REPORTED

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: 353201-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Sep-2008	13-Sep-2008	4	05-Aug-2009	06-Aug-2009	NC		19-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Abdominal pain, Acne, Anal fissure, Attention deficit/hyperactivity disorder, Autoimmune disorder, Bacteria urine identified, Biopsy kidney, Blood albumin decreased, Blood iron decreased, Blood urine present, C-reactive protein increased, Chest pain, Constipation, Contusion, Cough, Cryoglobulins present, Dysmenorrhoea, Haematochezia, Henoch-Schonlein purpura, Herpes virus infection, IgA nephropathy, Immunology test, Insomnia, Joint swelling, Kidney fibrosis, Nephritis, Oedema peripheral, Oral contraception, Orthostatic proteinuria, Pain, Pain in extremity, Peripheral coldness, Platelet count increased, Pneumonia, Polymerase chain reaction, Premenstrual syndrome, Protein total increased, Protein urine present, Pyrexia, Rash, Rash pustular, Red blood cell count decreased, Red blood cell sedimentation rate increased, Renal impairment, Sunburn, Temperature intolerance, Tendon injury, Urinary sediment present, Urinary tract infection, Viral upper respiratory tract infection, Vomiting, Wheezing, White blood cell count decreased

Symptom Text: 48 hours after the vacination of Gardasil, I has a reaction. My legs swelled and I had small red bumps all over my legs. I couldn't walk because of the pain and large amout of swelling in my knees and ankles. About 8 days after I had severe abdominal pain with vomiting and fever. I went to the doctor about a week after the shot because my legs were swelling all over and so were my elbows. The dots were spreading and they stung. She looked and examined me and we concluded I had HSP. It's an autoimmune desease that causes the blood veins to pop and leak. It is supposed to go away after 4-8 weeks. I have had it since Sep. 11th of 2008. We went to a skin doctor to make sure and he took a biopsy of my leg in 2 places and it was in fact HSP. About a month or 2 after we found out what I had, we started noticing I got sick very easily. I had my blood and urine tested and the doctors saw that I had an extremely high level of protein and blood in my urine. In the blood they took they saw that my iron was low and I had a low white blood cell count. We kept testing one or twice every 2 or 3 weeks. The protien and blood went up and down but was never at a normal or healthy amount. We then went to a doctor. He looked at my urine and blood and decided to preform a kidney biopsy. He saw that I had scarring on my kidneys and found that I have an IgA protien that causes my kidneys to overwork. I was put on blood pressure medicine and bottomed out so we stopped that. We are still to this day trying to find out what to do about the situation. We've also been to an allergist. She saw that the ingredients in Gardasil along with the protien in my body are reacting. I can't take any medication because I might have a reaction. Plus it goes to my kidneys which could cause damage. I might be put on steroids but we aren't sure. I just hope more people know about Gardasil before someone else gets what I have or worse. 8/17/09 PCP medical records received DOS 8/12/08 to 7/13/09. Assessment: Henoch-Schoenlein Purpura. Patient presents wit

Other Meds: none

Lab Data: in the skin biopsy we found that i had hsp. kidney biopsy showed protein and scarring. it was all un normal. 8/17/09 PCP medical records received DOS 8/12/08 to 7/13/09. LABS and DIAGNOSTICS: ANA (+). Urine culture (+) - E. coli. Urinalys

History: none. 8/17/09 PCP medical records received DOS 8/12/08 to 7/13/09. Hyperhydrosis, allergic rhinitis, recurrent otitis media, chronic constipation, GERD. 8/17/09 Consultant records and labs received DOS 11/18/08 to 8/10/09. Ear infections. Dental extraction.

Prex Illness: none. 8/17/09 PCP medical records received DOS 8/12/08 to 7/13/09. Oral candidiasis, Diflucan. Hyperhydrosis.

Prex Vax Illns:

Vaers Id: **353217-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	30-Jul-2009	30-Jul-2009	0	05-Aug-2009	17-Aug-2009	--		17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Asthenia, Fatigue, Renal pain

Symptom Text: Severe stomach pain and weakness. Very tired and barely able to get out of bed. Kidney pain.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **353225-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	30-Jun-2009	30-Jun-2009	0	05-Aug-2009	17-Aug-2009	DC		17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	2	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB236AA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Body temperature increased, Chills, Dizziness, Dyspnoea, Pain

Symptom Text: On the day of the vaccine was given, the patient developed chills, lightheadedness, dizziness, weakness and body aches. She also complained of shortness of breath. Temp was 105 degrees. Felt better in morning, consulted with provider by phone who advised her to increase fluids, take TYLENOL and call if worsens.

Other Meds:

Lab Data: none

History: obesity

Prex Illness: no specific illness

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353226-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Aug-2009	04-Aug-2009	0	05-Aug-2009	17-Aug-2009	PA		17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Nausea, Pharyngeal oedema

Symptom Text: Patient given GARDASIL vaccine about 4:00 PM. At about 4:10 PM patient states throat swelling, unable to breath, nausea. Patient out in supine position for about 15 minutes with frequent checks. Felt much better - release to parent.

Other Meds: BENTYL 2O mg

Lab Data:

History: IBS

Prex Illness: None

Prex Vax Illns:

Vaers Id: **353251-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.4	F	Unknown	30-Jul-2009		06-Aug-2009	11-Aug-2009	--		11-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Depression, Menstrual disorder

Symptom Text: My daughter had serious problems with her period had to be put on birth control, and now she is in the hospital with depression at 14 years old she never had this problem until after she had this shot, I wish I had never let her get this shot, and now she will have to take medicine for depression and anxiety for we don't know how long I just know that she never had this problem until after she had this shot.

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353262-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-May-2009	10-May-2009	6	06-Aug-2009	21-Aug-2009	OR	OR200931	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Genital swelling, Lymph node pain, Oedema peripheral, Pain in extremity, Urticaria

Symptom Text: Within one week of vaccination the client had a sore swollen arm and also developed hives along both labias and swollen, tender inguinal lymph glands.

Other Meds:

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353264-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Jul-2009	23-Jul-2009	0	06-Aug-2009	18-Aug-2009	VA		18-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2872AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1715X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Following vaccines, episode of syncope followed by brief seizure 2-3 seconds. Recovered fully without meds.

Other Meds: YAZ

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 353273-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Mar-2009	03-Apr-2009	4	06-Aug-2009	07-Aug-2009	FR	WAES0907USA04838	07-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0160X	0	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Neuropathy peripheral, Vaccine positive rechallenge

Symptom Text: Information has been received from a Health Authority (ref. # 2009-02926) concerning a 16 year old female patient with no pertinent medical history reported who on 30-MAR-2009 was vaccinated with the first dose of GARDASIL (Lot # 0160X and Batch # NJ30960) intramuscularly into her left arm. On 03-APR-2009, she developed a neuropathy of the right arm. She received the second dose of GARDASIL (Lot # 1648U and Batch # NH55600) via intramuscular route on 08-JUN-2009. In the following days she developed a neuropathy of the right leg. Laboratory work-up was complete and without particularity. A MRI was planned. There was no other information. At the time of reporting, the patient had not recovered. The Health Authorities considered that causal relationship between neuropathy and the vaccination as possible in the absence of other etiologies. A corrective version was created on 31-JUL-2009 to rectify the batch number of the first dose (NJ30960 instead of NJ20960). The primary reporter considered neuropathy to be significant disability/disabling. Other business partner numbers include: E2009-06530. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 353274-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	15-Aug-2008	20-Nov-2008	97	06-Aug-2009	07-Aug-2009	FR	WAES0907USA05737	07-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bladder diverticulum, Cystitis haemorrhagic, Haematuria

Symptom Text: Information has been received from a physician concerning a 26 year old female without mentioning anything about her past medical history who on 15-AUG-2008 and 06-NOV-2008 was vaccinated IM 0.5 mL with the first and second dose of GARDASIL (lot# not reported), respectively. Concomitant therapy was not reported. At 14 days after the second dose (on 20-NOV-2008), the patient developed hematuria and after echography and urography it was established Vesical (urinary bladder) diverticulum diagnose. The events of hemorrhagic cystitis and secondary vesical (urinary bladder) diverticulum required hospitalization. After treatment with CIPRINOL injectable 1 vials at 12 hours and amikacin injectable 1 vials at 12 hours in period 20-NOV-2008 to 04-DEC-2008, given for hemorrhagic cystitis and secondary vesical diverticulum, the symptomatology - hematuria remitted. On 15-DEC-2008, the patient recovered from hemorrhagic cystitis and secondary vesical (urinary bladder) diveritculum and on an unspecified date was discharged. The action taken with GARDASIL was reported as discontinued. The reporting physician felt that hemorrhagic cystitis and secondary vesical (urinary bladder) diveritculum were related to therapy with GARDASIL, as there was no any other reason for above described adverse events. Additional information is not expected.

Other Meds: Unknown

Lab Data: abdominal ultrasound, ??08, image suggesting vesical (urinary bladder) diveritculum; urinary system X-ray, ??08, image suggesting vesical (urinary bladder) diveritculum; urine culture, 20Nov08, negative; sterile

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **353275-1 (S)** **Related reports:** 353275-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Aug-2007	01-Aug-2007	0	06-Aug-2009	07-Aug-2009	PA	WAES0908USA00058	29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Acanthosis nigricans, Anaemia, Anger, Arthralgia, Complex regional pain syndrome, Contusion, Cyanosis, Enthesopathy, Gait disturbance, Joint effusion, Joint stiffness, Juvenile arthritis, Meniscus lesion, Mood swings, Muscular weakness, Musculoskeletal pain, Neck pain, Obesity, Oedema peripheral, Pain in extremity, Pneumonia, Sleep disorder, Smear cervix abnormal, Stress, Vaginal lesion, Wheelchair user, Wheezing

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter allergy to cinnamon and with a history of an allergic reaction (eye redness) to neomycin (manufacturer unknown) who in August 2007, was vaccinated with first 0.5mL dose of GARDASIL (route and lot number not reported). There was no concomitant medication. After a couple of days the patient experienced severe joint pain that she could not get up from bed and was unable to walk. Patient was given steroid injection in her feet and knees and for almost a year she was in wheel chair. The patient was given the second dose of GARDASIL (route and lot number not reported) in August 2008 and in November 2008, she was diagnosed with "polyarticular JIAR (Rheumatoid arthritis)". The patient's mother also stated that her daughter had abnormal cervical cells and small vaginal lesion. The patient's mother stated that soon her daughter will be getting steroid injection on her hands because she is unable to lift them. At the time of reporting the patient had not recovered from the events. Upon internal review polyarticular JIARS+ (Rheumatoid arthritis) and unable to walk were considered to be disabling. Additional information has been requested. 8/24/09 Consultant records received DOS 8/20/08 to 8/4/09. Assessment: Enthesopathy, amplified musculoskeletal pain. Polyarticular JIA RF(+). Patient with acquired acanthosis nigrans and obesity presents with knee, foot and neck pain. 'Walks like a duck'. Feet swollen. Nighttime awakenings secondary to pain. Stressed. Enthesitis multiple sites lower extremities and back. Torn medial menisc knee. Joint effusion. Anemia. Moodiness, anger and bruising. Joint stiffness. Feet turn blue. Wheezing. Pneumonia. Shoulder pain. Limp.

Other Meds: None

Lab Data: Unknown. 8/24/09 Consultant records received DOS 8/20/08 to 8/4/09. LABS and DIAGNOSTICS: Complement 199 (H). Sed Rate 115 mm/h (H). Rheumatoid Factor 24 IU/mL (H). CCP (+). ANA (+). MRI Feet - Abnormal, consistant with JIA. CHEM - Globu

History: Eye redness. 8/24/09 Consultant records received DOS 8/20/08 to 8/4/09. Sushi Reaction. Allergies to yellow jacket venom, neomycin, Sudafed, cinnamon. Self inflicted injury (cutting), Scanty menstruation. Scoliosis. Convulsions. Seborrheic dermatitis. Overweight. Seizures.

Prex Illness: Allergic reaction to antibiotics; Food allergy

Prex Vax Illns:

Vaers Id: **353275-2** **Related reports:** 353275-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2008	Unknown		09-Sep-2009	21-Sep-2009	NJ		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Polyarthritis, Respiratory failure

Symptom Text: Seen 4/29/08 with joint pain of approx 3 mo. time - eventually diagnosed with RF & polyarthritis.

Other Meds:

Lab Data: Attached

History: Bee venom allergy, neomycin; Sudafed; Cinnamon

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353282-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	10-Jun-2009		06-Aug-2009	18-Aug-2009	--		02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Pain

Symptom Text: Severe fatigue and soreness.

Other Meds:

Lab Data:

History: asthma; allergies

Prex Illness:

Prex Vax Illns:

Vaers Id: **353305-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Aug-2009	06-Aug-2009	0	06-Aug-2009	17-Aug-2009	NE		18-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Dyskinesia, Immediate post-injection reaction, Pallor

Symptom Text: APPROXIMATELY 2 MINUTES AFTER RECEIVING IMMUNIZATION PT BE CAME WEAK AND DIZZY. ACCORDING TO FATHER PT "SLUMPED OVER AND JERKED A FEW TIMES". PT NOTED TO BE VERY PALE.

Other Meds: None

Lab Data: INITIAL VITALS: B/P 104/59 HR 33 R 14 SPo2 98% -HEART MONITOR SHOWED NORMAL SINUS RHYTHM. PT WAS PLACED IN TRENDELENBURG POSITION AND OXYGEN WAS ADMINISTERED AT 2L NASAL CANNULA. AFTER ABOUT 20 MINUTES PT SAID SHE FELT BACK TO BASELINE. V

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **353307-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jul-2009	16-Jul-2009	0	06-Aug-2009	17-Aug-2009	AL	AL0911	18-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0570Y	1	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB281BB	1	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	1	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2689AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Fatigue, Loss of consciousness, Urticaria, Vomiting

Symptom Text: 7/27/09 Came in to HD c/o side effects since vaccination. Symptoms: dizziness (7/16/09), vomitting (7/22/09), passed out (7/23/09), hives on chest, remains weak and tired. Referred to MD. Note: Patient also participates in band practice

Other Meds:

Lab Data: None

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353315-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Oct-2008	16-Nov-2008	34	06-Aug-2009	17-Aug-2009	TX		20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0570X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Abdominal tenderness, Activities of daily living impaired, Arthralgia, Asthenia, Diarrhoea, Disturbance in attention, Excoriation, Fatigue, Feeling abnormal, Headache, Nausea, Oropharyngeal pain, Pain, Photophobia, Viral infection

Symptom Text: On 11/16/08, pt went about her day as normal, but became very tired quite suddenly around 5:00 in the evening. She went to bed to rest (something she rarely did until this point). After a couple of hours we attempted to wake her to attend church, a favorite activity, and she wanted to continue sleeping. We let her sleep until the next morning. We made her get up and prepare for school, but before she left, she complained of tiredness, headache, and sore throat, and we allowed her to stay home from school. She remained in bed for ten days, only getting up to go to the bathroom, shower, or go to the doctor. We encouraged her to sit up in a chair or even lie down in another room to help increase her energy level, but she did not have the strength for more than a few minutes. During this time the headache and sore throat remained, along with upper abdominal pain (left side right under ribs). The symptoms gradually improved, and pt was much better by the end of the first week of December. From then until the middle of January, pt continued to report mild symptoms, including fatigue and abdominal pain, but she was able to go about her normal activities. In mid January, pt came home from school, went to bed, and would not get up until morning. She went to school the remainder of that week with moderate symptoms, only because she was taking mid-term exams. Since then, pt has had three more occurrences of symptoms, missing one and two days of school. During these periods she has complained that light hurts her eyes. Upper abdominal pain, headaches, and sore throat recur periodically. Pt has also complained of periods of "feeling out-of-it", or not being able to concentrate at different times since mid-December. She has also stated that her legs "fall asleep" often. To the best of my knowledge, she has never had fever during this time. In July she received five injections (HPV/Meningitis/DPT/Varicella/HepA), and two in October (HPV/Influenza). Lot number for July 2008 HPV vaccine was 1757U.

Other Meds:

Lab Data: Lab tests performed, all with normal results: Monospot, EBV titers, CBC, urinalysis, pancreatic enzymes. Many other blood tests with normal results. Biopsy performed during endoscopy in June 09 showed mild chronic gastritis. Two abdominal

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **353330-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Aug-2009	06-Aug-2009	0	06-Aug-2009	19-Aug-2009	MI		19-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB296AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2670AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0653X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Pallor, Syncope

Symptom Text: Became pale 5 min after injection. Legs elevated. Fainted in chair. Eased down to floor by staff x 2. Easily aroused, oriented. BP 107/62. Skin warm, dry. CRT < 3 sec. Rested on floor x 5 min. Rested in chair x 10 min. Given juice/crackers. No injury sustained. Left with mother in stable medical condition.

Other Meds: None

Lab Data:

History: Pediazole

Prex Illness: None

Prex Vax Illns:

Vaers Id: **353335-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Aug-2009	05-Aug-2009	0	06-Aug-2009	19-Aug-2009	CA		01-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF471AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Repetitive speech, Syncope, Tremor

Symptom Text: About 4 pm, pt was at a restaurant, felt lightheaded, and was trembling. She stood and passed out. Upon awakening pt kept repeating herself over and over. Has hx of absence sz , cut off DEPAKOTE x 3-4 years. Says she feels like she had a sz. 9/29/09 PCP medical records received DOS 8/5/2009. Assessment: Syncope. Call from patient's mother. Patient felt light headed, stood and fainted. Kept repeating herself.

Other Meds: None

Lab Data:

History: Hx absence sz. Seizure.

Prex Illness: Atopic dermatitis. Rash under nose.

Prex Vax Illns:

Vaers Id: **353370-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Jul-2009	06-Jul-2009	0	07-Aug-2009	10-Aug-2009	OH	WAES0908USA00060	10-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aura, Blindness, Catatonia, Convulsion, Reaction to previous exposure to any vaccine

Symptom Text: Information has been received from a physician concerning a female with a history of experiencing aura of blindness and prevaccination anxiety after previous vaccines (unspecified which ones) and no known drug allergies, who on an unspecified date was vaccinated intramuscularly with first 0.5mL dose of GARDASIL (lot number 659054/0315Y). Concomitant therapy included MENACTRA. "After receiving the vaccine", the patient started experiencing an aura of blindness and proceeded to have a catatonic movement that went into a seizure. The patient recovered shortly after. No lab tests were performed. The patient did not seek medical attention. Upon internal review seizure was determined to be other important medical events. Follow up information was received from a registered nurse. It was reported that the 16 year old female patient has an allergy to Amoxicillin (hives) and a history of the aura of blindness and feeling strange after her vaccination with ADACEL, 3 summers ago (date not provided). The patient's mother reported that her daughter "last time" (3 summers ago) after she got a vaccine, she experienced the aura of blindness after they got out to the car. She did not loose consciousness, but felt really strange. The patient was administered GARDASIL (lot number 659054/0315Y, Expiration date 13-JUL-2010) on 06-JUL-2009. Concomitant medications included ibuprofen PRN and MENACTRA, also given on 06-JUL-2009. The patient was observed in the physician's office saying she was having an aura of blindness, she could not see and then proceeded to become catatonic and the went into a seizure. The registered nurse reported that she recovered shortly after, and was able to go home with no problems. The registered nurse reported that as far as she knows, the patient had not experienced any more seizure activity since 06-JUL-2009. She further noted that as far as she knows, the patient has completely recovered and that she has not called into the office and has not been in to the office since 06-JUL-2009. Additional informatio

Other Meds: Ibuprofen

Lab Data: Unknown

History: Vaccination adverse reaction; Aura; Blindness; Anxiety; Penicillin allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **353371-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	20-May-2008	01-Jun-2009	377	07-Aug-2009	10-Aug-2009	FR	WAES0908USA00479	10-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aplastic anaemia, Bone marrow transplant, Chemotherapy, Condition aggravated

Symptom Text: Information has been received from a physician concerning a 21 year old female patient with a history of anaemia in the past detected during blood donation who was vaccinated with a third dose of GARDASIL (lot #, injection route and site not reported) on 20-MAY-2008. In summer 2008 the patient experienced an aplastic anaemia. She was treated with chemotherapy and in November 2008 a bone marrow transplantation was carried out. At the time of reporting the patient had recovered, she was in a good general condition under immunosuppressive therapy. The reporting physician sees a temporal relation to the vaccination. Dose 1 of GARDASIL was administered on 11-DEC-2007 and dose 2 on 29-JAN-2008. No adverse effect was reported. Upon internal review aplastic anemia was considered to be another important medical event. Other business partner numbers include: E200907406. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Anaemia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353385-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	29-Jul-2009	29-Jul-2009	0	07-Aug-2009	19-Aug-2009	IA	IA090012	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2907BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1604X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Restlessness, Swelling, Weight increased

Symptom Text: Pt received immunizations at 0800 at 2100 developed restlessness and extreme aching pain from head to toe. Took 2 ASA and 3 hr later took 2 ibuprofen. Felt good enough to sleep woke up feeling fine at 0900 7/30/09. Skin was extremely sensitive at night as well. This week-body puffy all over and weight gain of 8 lbs.

Other Meds:

Lab Data:

History: Wheat sensitivity; Mold allergies; Tree pollen

Prex Illness:

Prex Vax Illns:

Vaers Id: **353404-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Aug-2009	06-Aug-2009	1	10-Aug-2009	19-Aug-2009	MI		19-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1502F	1	Unknown	Subcutaneously	
	VARCEL	MERCK & CO. INC.	1211X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye swelling, Oral pruritus, Paraesthesia oral, Pharyngeal oedema, Swelling face

Symptom Text: Client received 1st GARDASIL and 2nd VARIVAX vaccines afternoon of 8/5/09, experienced swelling of face, eyes, throat, itchy and tingling in mouth - difficulty speaking, taken to ER 12am 8/6/09

Other Meds:

Lab Data:

History:

Prex Illness: Eczema

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353415-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Jul-2009	04-Aug-2009	4	07-Aug-2009	19-Aug-2009	CA		20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2683AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3070AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Pruritus generalised, Rash generalised, Skin warm, Swelling

Symptom Text: Four days after vaccines (8/4/09), teen developed pruritus all over body at about 1pm. Five days after vaccines, teen developed red, itchy, warm, swollen rash all over body (including scalp & ears). Rash resolved without medications.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353418-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Aug-2009	06-Aug-2009	0	10-Aug-2009	20-Aug-2009	CA		20-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1497X	0	Left arm	Unknown	
MNQ	SANOFI PASTEUR	U2906AA	0	Left arm	Unknown	
TDAP	SANOFI PASTEUR	C3098AA	0	Unknown	By Mouth	
VARCEL	MERCK & CO. INC.	0478Y	1	Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB343AA	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Pallor

Symptom Text: Pt was nervous prior to receiving vaccinations and after 5th immunization pt stated "I feel weak". Color from lips went pale. Gave pt orange juice. Pt's mother said daughter had not eaten since breakfast. Applied cold compress to neck. Took vital signs. Vital signs within normal range. MD notified. MD assessed pt. MD released pt to parent. Advised pt. to eat prior to vaccinations per MD.

Other Meds: None

Lab Data: Vital signs, within normal range

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353459-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	28-Jul-2009	28-Jul-2009	0	07-Aug-2009	17-Aug-2009	TX		18-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient had syncope ~ 10 min after receiving the vaccine. At the same time was watching her sibling having blood drawn.

Other Meds:

Lab Data: PS OX = 100% Blood glucose = 79mg

History:

Prex Illness: All. Rhinitis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353484-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Aug-2009	06-Aug-2009	0	07-Aug-2009	17-Aug-2009	CA		18-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0726Y	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: fainted as leaving clinic after receiving Gardasil and varicella- event happened in clinic

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353491-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Aug-2009	04-Aug-2009	1	08-Aug-2009	18-Aug-2009	CA		18-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injection site pain, Paraesthesia

Symptom Text: Tingling and numbness in both hands and feet for over 12 hours. Soreness at the injection site continues.

Other Meds: n/a

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **353508-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Feb-2008	Unknown		10-Aug-2009	11-Aug-2009	FR	WAES0908USA00654	11-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0277U	2	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Circulatory collapse, Fatigue, Headache, Laboratory test, Myalgia, No reaction on previous exposure to drug, Pain in extremity

Symptom Text: Information has been received from Health Authority on 31-Jul-2009 under the reference number PEI2009016641. It was reported that an 18-year-old female patient who on 12-APR-2007 was vaccinated in the upper arm with the first dose of GARDASIL (lot# 1341F) and on 14-JUN-2007 was vaccinated in the upper arm with the second dose of GARDASIL (lot# 1341F). Dose 1 and Dose 2 were well tolerated. On 12-FEB-2008, the patient was vaccinated with the third dose of GARDASIL (lot#0277U) into the left upper arm. In the end of Feb-2008 the patient experienced exhaustion, pain in limb, circulatory collapse, myalgia, arthralgia and headache. The patient was hospitalized. Laboratory testing and special heart examinations were carried out. Results not reported. Viral infection was ruled out (no lab findings specified). The patient was treated with azithromycin which lead to a worsening of symptoms. At the time of reporting to HA the patient had not recovered. Other business partner number included: E200907698. FILE CLOSED.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353512-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2009	Unknown		10-Aug-2009	11-Aug-2009	FR	WAES0908USA00660	11-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal distension, Alopecia, Anorexia, Blood test, Constipation, Dizziness, Feeling cold, Feeling of body temperature change, Hot flush, Hypoaesthesia, Malaise, No reaction on previous exposure to drug, Nuclear magnetic resonance imaging, Paraesthesia, Weight decreased

Symptom Text: This case was initially reported to authority by a health care professional on 31-Jul-2009. This case concerns a female patient (age not reported). Details of the patient's medical history and concomitant medication have not been reported. The patient received the first dose of GARDASIL on January-09 without any problems. The patient's sister received the GARDASIL at the same time without any problem. On an unspecified date, but when the dose was due, the patient received the second dose of GARDASIL (batch#, lot#, route and site not reported). On an unspecified date but following the second dose, the patient became very ill for a number of months with hair loss, which was coming out in lumps, weight loss, numbness and tingling in her arm, dizziness, loss of appetite, feeling full and bloated, cold and constipated and hot and cold flushes. The patient underwent a magnetic resonance scan (MRI) and unspecified blood tests (results not reported). The patient outcome is unknown. The patient and her sister refused vaccination with the third dose of GARDASIL. Upon internal review this case has been upgraded to serious due to the events of dizziness, numbness and tingling. Other business partner number included: E200907764. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353513-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Jun-2009	Unknown		10-Aug-2009	11-Aug-2009	MI	WAES0908USA00379	11-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning a 19 female patient who on 12-JUN-2009 was vaccinated with the second 0.5ml dose of GARDASIL (lot number, route and site not reported). Subsequently, the patient experienced seizure after getting second dose of GARDASIL. The patient had sought unspecified medical attention. At the time of reporting, the patient's outcome was unknown. The patient did not have any adverse event from the first dose of GARDASIL. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **353514-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Jun-2009	22-Jul-2009	29	10-Aug-2009	11-Aug-2009	AL	WAES0908USA00387	27-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2872AA		Left leg	Unknown	
	HPV4	MERCK & CO. INC.	1312X	0	Right leg	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Adverse drug reaction, Akathisia, Anxiety disorder, Blunted affect, Decreased appetite, Dehydration, Drug exposure during pregnancy, Hallucination, auditory, Hyperventilation, Intensive care, Major depression, Mental disorder, Mydriasis, Nausea, Psychomotor retardation, Shock, Social avoidant behaviour, Social problem, Speech disorder, Staring, Suicidal ideation, Thought blocking, Unresponsive to stimuli, Vomiting

Symptom Text: Information have been received from the register nurse and a hospital central service technician, for GARDASIL, a Pregnancy Registry product, concerning an 18 year old female patient who on 23-JUN-2009 was vaccinated with a first dose of GARDASIL (lot#661846/1312X, route and site not reported) and a dose of MENACTRA (Sanofi Pasteur, lot#U2872AA). The patient was pregnant, the menstrual period was in May 2009, and the estimated delivery date was 05-Feb-2010. The hospital central service technician who was the patient's grandmother reported that the patient did not want to pregnant and was experiencing multiple relationship problems. "Something happened to her after she became pregnant. She did not sound like herself". On 22-JUL-2009, the patient contacted her grandmother and reported she was hyperventilating. The patient's father took her to the hospital on 23-JUL-2009 and she was admitted. On 24-JUL-2009, the patient was placed in the ICU. On 25-JUL-2009, she was transferred to the crisis unit. The grandmother visited the patient on 01-AUG-2009. The patient's eyes were dilated and she only communicated with a few words instead of complete sentences or by shaking her head. The nurse said that the patient was in a type of shock and was experiencing a chemical imbalance. At the time of reporting, the patient did not recover and was still hospitalized. Additional information has been requested. 8/24/09 Hospital records received DOS 7/23/09 to 8/10/09. Assessment: Major depressive disorder, anxiety disorder, pregnancy. Patient presents with psychomotor slowing. Stares for extended periods of time without answering. Thought blocking. Not responding to internal stimuli. Eating poorly, nausea and vomiting. Affect blunted. Dehydrated. Auditory hallucinations and suicidal ideation. Haldol - acathesia. ICD-9 Codes 648.43 Mental disorder complicating pregnancy antepartum condition or complication, 296.24 Major depression single episode severe with psychotic behavior, 300.0 Anxiety states, 646.63 Genitourinary tract i

Other Meds:

Lab Data: Unknown. 8/24/09 Hospital records received DOS 7/23/09 to 8/10/09. LABS and DIAGNOSTICS: Ultrasound - Pregnancy. CBC - WBC 18.5 X10*3 (H) RBC 3.85 X10*6 (L) HGB 11.7 g/dL (L) HCT 34.0% (L) NEU 14.5 X10*3 (H) Monocytes 1.3 X10*3 (H) Segs 77

History: 8/24/09 Hospital records received DOS 7/23/09 to 8/10/09. Sexually and physically abused. Alcohol use. Marijuana use. Blunt trauma to leg. Loss of consciousness.

Prex Illness: Pregnancy NOS (LMP = 5/1/2009)

Prex Vax Illns:

Vaers Id: **353515-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	01-Apr-2009		10-Aug-2009	11-Aug-2009	--	WAES0908USA00562	11-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Rash, Swelling

Symptom Text: Information has been received from a focus group researcher concerning a 17 year old female who was vaccinated with GARDASIL. In April 2009, the patient experienced rash, swelling, nausea and dizziness. The reporter noted that therapy with GARDASIL was discontinued. The patient's rash, swelling, nausea and dizziness diminished within 3 days after stopping GARDASIL. The reporter considered the rash, swelling, nausea and dizziness to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 353516-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Oct-2007	24-Oct-2007	1	10-Aug-2009	11-Aug-2009	KS	WAES0907USA02626	07-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Convulsion, Cough, Decreased appetite, Headache, Hyperventilation, Loss of consciousness, Neck pain, Road traffic accident, Syncope, Tricuspid valve incompetence

Symptom Text: Information has been received from a physician concerning an approximately 17 year old female who in 2007 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot# not reported). The physician reported that the patient had been experiencing syncope episodes after receiving GARDASIL in 2007. Two days after receiving her first dose of GARDASIL, the patient experienced her first syncope and was admitted into a hospital. The hospital name and the length of stay were unknown. The patient was currently seeing doctor and being treated with "seizure medications." The patient finished the 3 doses GARDASIL series. At the time of reporting, the patient was recovering. Additional information has been requested. The Health Care Professional contacted during telephone follow-up could not supply the following information: dates of vaccination/therapy, lot numbers, date of event, hospital name. No further information is available at this time. Follow up information has been received from a physician via medical records. On 23-OCT-2007, at 02:30 pm the patient who was home schooled, and non-smoker and did not use illicit substances with depression, frequent headache, and allergy to sulfa and BACTRIM, amoxicillin and AUGMENTIN, and erythromycin, seasonal allergy, and a medical history of tonsillectomy, and with a family history of asthma (mother) and thyroid cancer (father), and with an infected ingrown toe nail in the right big toe at the time of vaccination, was vaccinated with the first dose of GARDASIL (lot# 659435/1265U), intramuscularly in the left deltoid. On 22-FEB-2008, at 02:50 pm, the patient was vaccinated with the second dose of GARDASIL (lot# 659962/1740U), intramuscularly in the left deltoid. On 09-JUN-2008, at 03:05 pm the patient was vaccinated, with the third dose of GARDASIL (lot# 660391/0063X), intramuscularly in the left deltoid. Concomitant therapy included ZYRTEC, LEXAPRO and ZANTAC. The physician reported that the patient had a headache on 24-OCT-2007. The physician reported that the patient noted that

Other Meds: ZYRTEC; LEXAPRO; ZANTAC

Lab Data: echocardiography, 10/25/07, trace tricuspid regurgitation; electroencephalopathy, 10/25/07, short bursts of left temporal sharp activity during hyperventilation/isolated left temp sharp activ; head computed axial, 10/25/07, negative; diagno

History: Tonsillectomy. 9/15/09 Neurological consult records received DOS 11/07/07. Migraines. Depression.

Prex Illness: Infected toe; Sulfonamide allergy; Allergic reaction to antibiotics; Seasonal allergy; Non-smoker; Depression; Headache

Prex Vax Illns:

Vaers Id: **353517-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jun-2008	01-Oct-2008	107	10-Aug-2009	11-Aug-2009	IL	WAES0908USA00064	26-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2566AA		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Dyskinesia, Loss of consciousness, Muscle twitching, Pain in extremity, Partial seizures, Sensory loss, Tremor, Vision blurred

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter with no drug reactions/allergies who was vaccinated with the first dose of GARDASIL in "June 2008". The patient was vaccinated with meningococcal vaccine (manufacturer unknown) on the same day (Lot U2566AA). "Sometime in October 2008", the patient started having seizures. The patient was jerking sometimes and showing seizure episodes. The patient had some seizure attacks in "April 2009" and "June 2009". The patient was brought to the emergency room in "June 2009" and was not admitted in the hospital. The lab diagnostics studies performed: MRI, EEG, CAT SCAN. At the time of report the patient's status was not recovered. Follow-up information was received from a registered nurse indicated the patient received GARDASIL (Lot #660387/1967U) on 16-JUN-2008. Concomitant therapy included meningococcal vaccine (manufacturer unknown) (Lot #U2566AA). Follow-up information was received from a nurse assistant indicated that the patient had an EEG which was reported as "abnormal EEG" on 05-MAY-2009. On 12-MAY-2009 the patient had a MRI which revealed "Right frontal matter hyperintensity". On 14-MAY-2009 the patient was seen by a doctor and was placed on therapy with KEPPRA 750mg BID. The patient was instructed to not drive. The patient was to repeat the EEG and MRI in 6 months. The patient was to move to another state (date unknown) and instructed to find a treating neurologist when she moved. On 18-JUN-2009 the patient went to the emergency room due to "convulsions". The patient was not admitted to the hospital. Convulsion was considered to be an other medical event. Additional information has been requested. 8/12/09 PCP records received. In for PE with normal exam. Vaccines administered. 8/24//09 Neurological consult records received DOS 5/14/09. Assessment: Focal Seizures with possible secondary generalization. Patient presents for assessment of abnormal EEG. First episode of syncope 2/09 or 3/09. Twitching of body. Blurry vision. 2 w

Other Meds:

Lab Data: electroencephalography, 05/05/09, abnormal; magnetic resonance, 05/12/09, right frontal matter hyperintensity. 8/24//09 Neurological consult records received DOS 5/14/09. LABS and Diagnostics MRI Brain - abnormal, right frontal white matt

History: None. 8/12/09 PCP records received DOS 6/16/08. Torn Achilles. DOS 6/16/08. Assessment: Routine Physical Exam. Contraception. Skin freckling. 8/24//09 Neurological consult records received DOS 5/14/09. Left foot benign tumor removal.

Prex Illness:

Prex Vax Illns:

Vaers Id: 353518-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Nov-2008	09-Dec-2008	30	10-Aug-2009	11-Aug-2009	FR	WAES0908USA00116	11-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Musculoskeletal pain, Pain in extremity, Sensory disturbance

Symptom Text: Case received from the Health Authorities on 31-JUL-2009 under the reference numbers MA20091226 and 09-2228. Information has been received from an agency concerning a 14-year-old female patient who had been followed within a child in psychiatry environment from the age of 18 months to 12 years old received the first dose of GARDASIL (batch number not reported) via intramuscular route at the level of the left upper limb on 09-NOV-2008. One month later, she developed pain starting in the left upper limb, at the level of the scapular belt, then reaching the left leg, followed by right arm and then the right leg. After a consultation she was hospitalized from 27-JAN-2009 to 30-JAN-2009 at the Child Neurology Unit. The following work-up were performed and were normal: standard x-ray examination, left shoulder echotomography, shoulder MRI, cerebral MRI, 4 limbs electromyography, electroencephalography. Troponin, C-Reactive Protein, creatine kinase, lactic dehydrogenase, anti-Sm and anti-RNP antibodies, anti-SSA/Ro and anti-SSB/La antibodies, immunoglobulins M and immunoglobulins G were normal. Only the immunoglobulins A were a little high at 2.78. These pains, accompanied with sensitivity disorders, evoked a Parsonage-Turner syndrome but it was ruled out due to the resistance to corticotherapy. Final diagnosis was "rebel pain with a functional component". The teenager was treated with LAROXYL, EFFERALGAN CODEINE and MYOLASTAN following to a consultation to a pain center. At the time of report, the patient had not yet recovered. Sensory disturbance and pain in the joint involving the shoulder region, lower leg and limb were considered to be disabling. Other business partner numbers included E2009-07668.

Other Meds: Unknown

Lab Data: electromyography, ??Jan09, 4 limbs electromyography normal; electroencephalography, ??Jan09, normal; ultrasound, ??Jan09, left shoulder echotomography normal; X-ray, ??Jan09, normal; magnetic resonance imaging, ??Jan09, shoulder MRI normal;

History: Psychiatric symptom

Prex Illness:

Prex Vax Illns:

Vaers Id: 353519-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Jun-2009	07-Jul-2009	11	10-Aug-2009	11-Aug-2009	FR	WAES0908USA00119	11-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0772X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood product transfusion, Idiopathic thrombocytopenic purpura, Petechiae

Symptom Text: Case received from the Health Authorities in country on 30-JUL-2009 under the reference number L200907-506 and received through authority. A 12-year-old female patient had received the first dose of GARDASIL (lot # 0772X, batch # NK13910) via the intramuscular route on 26-JUN-2009 and 07-JUL-2009, she developed idiopathic thrombocytopenic purpura with petechiae and decreased platelet count. Her platelets level was found to be at 6,000 on 07-JUL-2009 and at 300,000 on 16-JUL-2009. She received corrective treatment with normal human immunoglobulins 800mg/kg via intravenous route. The patient recovered 9 days after onset of purpura. It was worth noting that the Health Authorities reported that vaccination had been administered 15 days before onset of idiopathic thrombocytopenic purpura, which was not consistent with time to onset between of date of vaccination and date of onset. The patient had no known clinical history, no previous history suggestive of viral infection and no previous history of adverse reaction to other drugs. The event was reported to be other important medical event. Other business partner numbers include E2009-07720. No further information is available.

Other Meds: Unknown

Lab Data: platelet count, 07Jul09, 6,000; platelet count, 16Jul09, 300,000

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353561-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Aug-2009	04-Aug-2009	0	10-Aug-2009	20-Aug-2009	VA		20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2922AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Head injury, Headache, Syncope

Symptom Text: 14 yo female fainted for seconds and fell back post vaccine admin. - head hit floor when fell - Required lying in exam room until able to get up without c/o HA or dizziness - Had only eaten a bagel in am and then run mile before appoint. Given coca cola to drink and hard candy.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353587-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	04-Aug-2009	04-Aug-2009	0	10-Aug-2009	20-Aug-2009	NC		20-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0100Y	1	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB296AA	1	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	AC52B0401BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Mydriasis, Syncope, Unresponsive to stimuli

Symptom Text: Pt fainted with assistance to floor. Posterior head was struck on fridge. Pupils dilated approx 7mm - pt was not following commands to squeeze hands or track movement. Symptoms lasted approx 30 seconds. Dr. in vaccine room prior to pt becoming responsive. Per mother pt has a history of fainting when seen blood.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **353588-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Aug-2009	04-Aug-2009	0	10-Aug-2009	20-Aug-2009	GA		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall, Gaze palsy, Head injury, Syncope

Symptom Text: My daughter received her 1st dose of GARDASIL IM. We then went to check out at the receptionist's window. My daughter fainted or had a stiffening type seizure, eyes rolled back in her head and she fell on the floor striking her head on a cement flower pot. We went by ambulance to the emergency room where she had to have a CT of her head and EKG. Thank God so far everything is ok. This was a nightmare.

Other Meds:

Lab Data: CT of her head was negative for subdural hematoma, EKG was NSR

History: healthy 12 year old female

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353590-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	05-Aug-2009	06-Aug-2009	1	10-Aug-2009	20-Aug-2009	TX		20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	6019Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1129X		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2992AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Skin warm, Swelling, Tenderness

Symptom Text: Reddened/ raised area. Warm to touch with tenderness - ADVIL given by caretaker - Warm compress applied - reaction appeared 8-6-09 to left arm.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353608-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	22-Jun-2009	24-Jun-2009	2	10-Aug-2009	20-Aug-2009	TN		20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash macular, Urticaria

Symptom Text: Approx. 2 days after the vaccine was administered the patient reports that she broke out in hives, all over her body but consentrated on the abdomen. She also had a blochy rash in addition. She reports itching, no fever. She did not seek medical attention. The hives lasted approx. 2 wks and the itching continued for approx. 1 month.

Other Meds: Prenatal vitamins (pt. postpartum)

Lab Data:

History: wellbutrin allergy

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353609-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	10-Aug-2009	10-Aug-2009	0	10-Aug-2009	20-Aug-2009	PA		20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Received Gardasil dose #2. Walked to waiting room and fainted. BP 118/60. Given ginger ale to sip. Denied dizziness. BP recheck 5 minutes later 108/50. Feeling better. Left office with mother.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **353615-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Aug-2009	10-Aug-2009	0	10-Aug-2009	20-Aug-2009	OH		21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0658Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0100Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Contusion, Ear haemorrhage, Fall, Fatigue, Immediate post-injection reaction, Injury, Loss of consciousness, Syncope, Tearfulness

Symptom Text: Immediately following HPV#2 and Varivax #2 (10:45 am) patient fainted and fell forward off of the exam table and hit her Left cheek, ear and knee on the ground. Her ear bled at the site of her earring. After being on the ground flat she regained consciousness within 45-60 seconds. She was confused for a few moments and tearful. Ice was applied to her cheek and she stayed and was observed for 15 minutes. She was told not to drive or go to work today and to call if she had vomiting, headaches or other changes. Mom is very upset. I called at 5:30 pm and patient is napping and other than having a bruise on her cheek (not swollen) and tired has no other worrisome signs. Mom wants a CT of brain and cheek done (she works in radiology at hospital). I do not think these are warrented at this time. She is angry I won't order them now and is going to file a report with the hospital.(she says.)

Other Meds: antibiotics s/p wisdom tooth extraction 5 days prior. I don't know what they are as they didn't know.

Lab Data:

History: None

Prex Illness: mild URI with runny nose for one day.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353629-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Jul-2009	27-Jul-2009	0	10-Aug-2009	20-Aug-2009	NJ		20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UF486AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	0312Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bradycardia, Syncope

Symptom Text: Syncope. Bradycardia - pulse < 40. Given oxygen.

Other Meds: None

Lab Data: EKG, Pulse ox, blood glucose

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353744-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Aug-2009	03-Aug-2009	0	11-Aug-2009	20-Aug-2009	IN		20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2733AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3249AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: C/o fainting

Other Meds: None

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353753-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Aug-2009	04-Aug-2009	0	11-Aug-2009	21-Aug-2009	TX		21-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB281BB	0	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	U2732AA	0	Unknown	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B036BA	4	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	0522U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: On 08/04/09 approx 10:10 AM vaccines administered tolerated well - nurse assisted client and mother to supply room to receive health information materials, from nurse. Nurse called to room and nurse observed client on floor, fainted and hit back of head onto wall. Client alert, oriented, assisted to chair, VS taken B/P 104 to HR = 88 - R=20, no swelling to head noted - ice pack applied. Referred to PCP - Treated with MOTRIN.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353755-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Jul-2009	29-Jul-2009	0	11-Aug-2009	21-Aug-2009	OH		21-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2819AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0229X	0	Unknown	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB312AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cardiac murmur, Echocardiogram, Electrocardiogram, Loss of consciousness, Pallor, Syncope, Vomiting

Symptom Text: Syncope, vomiting, grey skin tone. Syncope lasted ~20 sec, patient came to and combative, then began vomiting intermittently and skin tone grey X 30min. VSS called squad and transported to Children's Hospital. Patient continued to throw up in ambulance. Observed in ER. Specific testing not done due to patient's strong history of syncope. In the past patient had tilt table test for diagnosis of vasodepressor syncope. Recently (2/09) pt had EKG and Echo for innocent murmur before nasal surgery. Patient passed out every time in ENT's office when painful stimulus per mom.

Other Meds:

Lab Data:

History: Vasodepressor Syncope

Prex Illness: Hematuria

Prex Vax Illns:

Vaers Id: **353760-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Aug-2009	05-Aug-2009	1	11-Aug-2009	21-Aug-2009	IN		21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cheilitis, Fatigue, Gingivitis, Lip swelling, Lymphadenopathy, Oropharyngeal blistering, Pain, Stomatitis

Symptom Text: Body aches, fatigue, blisters inside mouth, swollen glands, sores on lips and gums, swollen lips.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **353763-1** **Related reports:** 353763-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Jun-2009	27-Jun-2009	2	11-Aug-2009	21-Aug-2009	NC		09-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Abdominal tenderness, Activities of daily living impaired, Decreased activity, Diarrhoea, Dizziness, Fatigue, Headache, Myoclonus, Palpitations, Phonophobia, Photophobia, Pyrexia, Syncope, Visual impairment, Vomiting

Symptom Text: Severe diarrhea w/in 48 hrs. of 3rd vaccine, vomiting, chronic fatigue, headache, abdominal pain, heart palpitations, sensitivity to light & noise. All except vomiting have continued. Low grade fever of "unknown origin". 8/14/2009 PCP records rec'd dated 7/20-8/3/2009 with dx: Headache. Fatigue. Abdominal Pain. Pt initially presented 7/20/09 with 2 week hx of headaches and abdomminal pain. Nausea associated with abd pain. Parent reports reduced activity level. F/U 8/1/09. Tenderness to palpation in RUQ. Returned 8/3/09 with worsening sx. MD notes sx began following HPV and TDaP vax in June. Reports need frequent breaks with activity, spending days in bed 2' to fatigue, dizziness, lightheadedness, seeing spots, epigastric pain, several episodes of syncope with myoclonic movements. Referred to cardiology and neurology.

Other Meds: LEXAPRO-20mg; VYVANSE-30mg; YAZ

Lab Data: CBC; sed rate checked; mono test; Lymes disease; abdominal ultrasound. Labs and Diagnostics: EEG WNL. Na+ 123, Cl- 94 both low. EBV capsid IgGAb (+), IGM (-), Nuclear IgG Ab (+).

History: allergic to mites, molds, aged cheeses. PMH: ADD, Anxiety, Sensory integration issues, env allergies. 9/24/09 Hospital operative report DOS 6/12/09. Recurrent tonsillitis, hypertrophic tonsils. Tonsillectomy performed. 10/8/09 Neurology and cardiology consults service dates 2/6/08 to 6/1/2009. ECG - Normal Sinus Rhythm. Sleep disorder Patient presents with hypersomnolence.

Prex Illness:

Prex Vax Illns:

Vaers Id: **353763-2 (S)** **Related reports:** 353763-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Jul-2008	Unknown		17-Aug-2009	18-Aug-2009	NC	WAES0908USA00887	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070K	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Condition aggravated, Diarrhoea, Fatigue, Headache, Heart rate increased, Nausea, Oropharyngeal pain, Pain, Pyrexia, Tonsillectomy, Vaccine positive rechallenge

Symptom Text: Information has been received from a health professional concerning her 18 year old daughter with no known allergies and a history of infectious mononucleosis ("a few years ago") who on unspecified dates was vaccinated with the first and second dose of GARDASIL (lot number not reported). Around 24-JUL-2009 (also reported as 26-JUN-2009) the patient was vaccinated with the third dose of GARDASIL (lot number not reported). The patient experienced a little fatigue and pain after the first and second dose of GARDASIL. Same day therapy included a "HTP" vaccine (unspecified) ("a tetanus or other usual vaccine that is given before someone enters college"). Concomitant therapy included LEXAPRO. On approximately 28-JUN-2009, 2 to 3 days after the administration of the third dose, the patient experienced low grade fever, diarrhea (still occurred periodically), rapid resting pulse up to 150 (still occurred periodically), headache (occurred every day), chronic severe abdominal pain and severe fatigue. The patient got her tonsils out 2 weeks prior to receiving the third dose of GARDASIL and experienced fatigue after the tonsils were removed. The fatigue became worse after the administration of the third GARDASIL. Test for mononucleosis, complete blood cell count, Lyme disease, abdominal ultrasound and sedimentation rate were performed and every test had been coming back negative. As of 05-AUG-2009 the patient had not recovered. Additional information has been received from a physician and a head nurse concerning the 18 year old female patient. On 08-JUN-2009 the patient was seen by the physician for a physical prior to college admittance. On 30-JUL-2008 she was vaccinated with the first dose of GARDASIL (lot number reported as 0070K, invalid for GARDASIL, but is a valid lot number for VARIVAX (Merck)). On 05-NOV-2008 the patient was vaccinated with the second dose of GARDASIL (lot number 661530/0575X). On 25-JUN-2009 (reported by the patient's mother as around 24-JUN-2009 and 26-JUN-2009) the patient was vaccinated with the

Other Meds: LEXAPRO

Lab Data: abdominal ultrasound, 07/20?/09, negative; Streptococcus group A, 07/08/09, negative; complete blood cell, 07/20/09, normal; metabolic marker test, 07/20/09, normal; plasma Epstein-Barr, 07/20/09, normal; Lyme disease assay, 07/24/09, norma

History: Infectious mononucleosis

Prex Illness:

Prex Vax Illns:

Vaers Id: **353782-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	07-Aug-2009	09-Aug-2009	2	11-Aug-2009	20-Aug-2009	PA		20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	3	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Inappropriate schedule of drug administration, Paraesthesia

Symptom Text: had 2 episodes of numbness and tingling of left arm and leg unrelated to the site of administration. this shot was given in the right arm. It was her 4 th shot. Other dates of shots were 3/23/07; 5/23/07;11/26/07 and 8/07/09. the last shot was given in error.

Other Meds: bcps

Lab Data: latest lab values done 8/10/09 were within normal limits except for neut%73.9(H) and lymph%20.1(L)

History: depression/anxiety/panic attacks

Prex Illness: here for a follow-up exam

Prex Vax Illns:

Vaers Id: **353790-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Aug-2009	07-Aug-2009	0	11-Aug-2009	20-Aug-2009	CA		21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0670Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria, Musculoskeletal pain, Pain in extremity

Symptom Text: Pt received HPV4 vaccine injection on 8/7/09 at about 4:30pm. She developed a 4-5 inch diameter area if hives around the injection site at about 9pm. She also has had a sore arm and shoulder. However, her mother said she had been jet sking all day the day before and that may account for the shoulder/arm discomfort. Mother gave her Benadryl at home and the hives went away. No other sx were noted.

Other Meds: Yasmin. Qvar. Albuterol.

Lab Data:

History: Amoxicillin. Asthma.

Prex Illness:

Prex Vax Illns:

Vaers Id: **353802-1 (S)** **Related reports:** 353802-2; 353802-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jul-2009	25-Jul-2009	9	11-Aug-2009	18-Aug-2009	NJ		20-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Malaise, Myalgia, Pain, Pyrexia, Rash

Symptom Text: Received vaccine 7/16/09. Dev rash on back 7/25 with malaise, body aches. Developed fevers to 103 on 7/28 which persisted, then developed rash on legs. The rash spread 8/3 to hands. Pain in muscles worsened. Rash became widespread by 8/10 fever, pain persisted.

Other Meds: SYNTHROID

Lab Data: Elevated AST, ALT, LFT; ESR 86, CRP 23.9. EBV c/w past infection, CMP (-), Hep A (-), Hep B (-), Parvovirus - old infection, Mycoplasma (-), Viral Cx (-), Low C4, C3

History: Hypothyroidism; Obesity

Prex Illness: No

Prex Vax Illns:

Vaers Id: **353802-2 (S)** **Related reports:** 353802-1; 353802-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jul-2009	25-Jul-2009	9	18-Aug-2009	19-Aug-2009	NJ	WAES0908USA01745	13-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Arthralgia, Asthenia, Drug eruption, Electrolyte imbalance, Grand mal convulsion, Hypersensitivity, Hypertension, Malaise, Nuclear magnetic resonance imaging abnormal, Pain, Pancytopenia, Pyrexia, Rash, Renal failure, Steroid therapy, Syncope, Urticaria

Symptom Text: Information has been received from a physician concerning a 18 year old female with hypothyroidism, obesity and no allergies who on 16-JUL-2009 was vaccinated with her first dose of GARDASIL (lot # 661846/1312X). Concomitant therapy included SYNTHROID. On 25-JUL-2007 the patient developed urticaria of hands and lower extremities, malaise, and body aches. The urticaria then became confluent, widespread, and the patient developed fever of 103-104F and joint pain. The patient was admitted to the hospital on 11-AUG-2009 and was being evaluated for systemic hypersensitivity syndrome. Testing had revealed splenomegaly, hepatomegaly, elevated aspartate aminotransferase (AST), alanine aminotransferase (ALT) and gamma-glutamyl transferase (GGT), elevated erythrocyte sedimentation rate (ESR) 86, elevated C-reactive protein, and low C4 and C3. The patient was being treated with hydration and unspecified antihistamines. Additional information has been received from the physician who saw this 18 year old patient on 06-AUG-2009, ran viral cultures which were negative, hepatitis A and C negative, Hepatitis B-fully immunized. A sonogram showed hepatomegaly and splenomegaly which were also present on exam. The patient was given Clindamycin in case this was a toxin mediated reaction. The patient was also seen by dermatologist in Doctor's office. Dermatologist thought rash and symptoms could of resembled drug or vaccine induced reaction but not the Stevens-Johnson syndrome (SJS) since no mucous membranes involved. On 12-AUG-2009, the physician reported that no other vaccines were given at the time that GARDASIL vaccine was administered (by the pediatrician's office) on 16-JUL-2009. On 06-AUG-2009, "at her worst", the patient's values were as follows: AST 76, ALT 200, GGT 375, ESR 86, and C-reactive protein 23.9 mg/dL. On 11-AUG-2009, the patient's C4 was less than 2.9 and C3 was 59. The patient remained in the hospital on 12-AUG-2009. Treatment included IV BENADRYL and ZANTAC. No steroids had yet been administered. The patient soug

Other Meds: SYNTHROID

Lab Data: ultrasound, 08/06/09, hepatomegaly and splenomegaly; serum aspartate, 08/06/09, 76; serum alanine, 08/06/09, 200; serum gamma glutamyl, 08/06/09, 375; erythrocyte, 08/06/09, 86; serum C-reactive, 08/06/09, 23.9 mg/d; component C4 test, 08/1

History: PMH: Hashimoto's thyroiditits, borderline diabetes

Prex Illness: Hypothyroidism; Obesity

Prex Vax Illns:

Vaers Id: **353802-3** **Related reports:** 353802-1; 353802-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		31-Aug-2009	01-Sep-2009	NJ	WAES0908USA04161	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Convulsion

Symptom Text: Information has been received from a physician concerning a young female patient (age unknown) who on an unknown date several weeks ago was vaccinated with a dose of GARDASIL (lot, route and site not reported). The patient's medical history, relevant concomitant medications, relevant past drug history were unknown. On an unknown date, after receiving GARDASIL, the patient developed seizures. The physician stated that the seizures were definitely seizures and not another related condition. On an unknown date, after GARDASIL vaccination, an magnetic resonance imaging (MRI) showed an acute disseminated encephalomyelitis with possible complications. The physician was planning on testing the seizures and acute disseminated encephalomyelitis as if these diseases states were happening. The physician stated that he could not necessarily implicate GARDASIL as the cause of those conditions. As of 22-AUG-2009, it was unknown if the patient continued to take GARDASIL, and the results of the seizures and acute disseminated encephalomyelitis were unknown. Upon internal review seizures and acute disseminated encephalomyelitis were considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance, ?/?/09, showed acute disseminated encephalomyelitis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **353803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	27-Jul-2009	27-Jul-2009	0	11-Aug-2009	21-Aug-2009	CO		21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint swelling

Symptom Text: A couple of hours after 1st shot, my left knee (which I've had 9 surgeries on, synvisc injection, and is arthritic) swelled up very large far 5 days straight and was unresponsive to wrapping, , electrodes + elevation.

Other Meds: CELEBREX

Lab Data:

History: 9 knee surgeries on meniscus/cartilage; Arthritis present

Prex Illness: None

Prex Vax Illns:

Vaers Id: **353830-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
52.0	F	15-Oct-2008	16-Oct-2008	1	06-Aug-2009	17-Sep-2009	--	WAES0810USA03399	17-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	PPV	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Pain, Sinus congestion

Symptom Text: Information has been received from a registered nurse concerning a 52 year old female co-worker with no known allergies or pertinent medical history who on 15-OCT-2008 was vaccinated with PNEUMOVAX 23. Concomitant therapy included GARDASIL 0.5 ml IM. The registered nurse reported that the patient developed unspecified body aches on 16-OCT-2008 and sinus congestion on 17-OCT-2008 after receiving PNEUMOVAX 23 on 15-OCT-2008. No other symptoms reported. The patient's unspecified body aches and sinus congestion persisted. The patient did not seek treatment. No lab diagnostics were performed. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353861-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Aug-2009	03-Aug-2009	0	12-Aug-2009	25-Aug-2009	MO	MO200917	25-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X		Left arm	Intramuscular	HEPA MNQ

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Pruritus generalised, Rash

Symptom Text: 15-20 minutes after injection client experienced itching at injection site. After about 2 hours had itching all over and had rash on cheeks. Took bath in epsom salts and took benadryl at bedtime. In a.m. - no further symptoms

Other Meds: TriSprintec oral daily (oral BC pill)

Lab Data: None

History:

Prex Illness: No

Prex Vax Illns:

Vaers Id: 353867-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		12-Aug-2009	13-Aug-2009	FR	WAES0908USA01100	13-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blood product transfusion, Lymphopenia, Thrombocytopenia, Vaccine positive rechallenge

Symptom Text: Information has been received from the Health Authorities on 31-JUL-2009: A 15 year old female patient with a history of HIV positive since her birth (mother to child contamination) was vaccinated with her 1st dose of GARDASIL (batch # not reported) in April 2009 (to be confirmed as date was also to be April 2008) and a dose of PNEUMOVAX (batch # not reported) on an unspecified date. After vaccination, her viral load was very slightly positive at 68 copies, but she experienced a marked decrease of CD4 T cells on a background of lymphopenia at 797/ml. She received the 2nd dose of GARDASIL (batch # not reported) in May 2009, after CD4 lymphocytes had increased. One month later, she developed thrombocytopenia and decreased CD4 T cells. She was hospitalized during one night to received intravenous injection of immunoglobulins. The patient was found to have platelet count at 6 on 24-JUN-2009, at 9 on 25-JUN-2009 and at 97 on 03-JUL-2009 (normal: 140-450g/l). In April 2006 (?) her CD4 T cells were at 0.19%. On 24-JUN-2009 her CD4 cells were at 0.478% and her viral load at 2964 copies/ml. At the time of reporting, the patient had not recovered. Other business partner numbers included E2009-07659.

Other Meds: Unknown

Lab Data: blood (CD3+ CD4+) T-cell count, 06?, 0.19%; blood (CD3+ CD4+) T-cell count, 24Jun09, 0.478%; plasma HIV RNA quantification, 24Jun09, 2964 copies/ml; platelet count, 24Jun09, g/l, decreased; platelet count, 25Jun09, gl, decreased; platelet c

History:

Prex Illness: HIV test positive

Prex Vax Illns:

Vaers Id: **353870-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Jan-2009	04-May-2009	114	12-Aug-2009	13-Aug-2009	--	WAES0908USA00614	10-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	1	Left arm	Intramuscular	FLUN HPV4

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Adverse drug reaction, Balance disorder, Convulsion, Drug level below therapeutic, Epilepsy, Fall, Fatigue, Gait disturbance, Gaze palsy, Grand mal convulsion, Headache, Migraine, Muscle rigidity, Muscle twitching, Postictal state, Reading disorder, Vomiting

Symptom Text: Information has been received from a physician concerning a 14 year old female with no pertinent medical history and no known drug allergies (NKDA) who on 04-NOV-2008 was vaccinated with the first dose of GARDASIL (lot# 660518/0572X, dose and route not reported) and a dose of VARIVAX (Merck) (661668/1194X, dose and route not reported). Concomitant vaccination on 04-NOV-2008 included hepatitis A virus vaccine (unspecified) (lot# AHAVB264AA) and FLUMIST (LOT# 500570P). The patient was vaccinated with the second dose of GARDASIL (lot# 660616/0570X, dose and route not reported) on 10-JAN-2009 and the third 0.5ml dose of GARDASIL (lot# 661846/1312X, injection) on 14-MAY-2009. The patient's first seizure was on 04-MAY-2009 (prior to the third dose of GARDASIL). A computed axial tomography (CT) scan done that day was negative. The patient was not admitted. The patient's next seizure (gran mal) was on 19-MAY-2009. An electroencephalography (EEG) done on that day was abnormal, showing spikes in the left anterior region supportive of seizure disorder. The patient was not admitted again. The patient went on to have additional seizures in the latter part of July 2009, for which she was admitted to hospital and was diagnosed as epileptic syndrome. On unspecified day, a magnetic resonance imaging (MRI) was performed but the results came back clear. Length of hospital stay was unknown. At the time of reporting, the patient was recovering. The patient was being treated with DILANTIN and TOPAMAX and being followed by neurology. It was reported that the condition was not considered life threatening. The physician could only say that the patient found it was hard to read regarding disability. Upon internal review, seizure and gran mal seizure were determined to be other important medical events. Additional information has been requested. 8/14/09 PCP and ER records received DOS 3/28/05 to 7/30/09. Assessment: Localization related epilepsy of left frontal origin. Breakthough Seizures. Subtherapeutic antiseizure levels. 5/04/09 -

Other Meds:

Lab Data: Computed axial, 05/04/09, negative; Electroencephalography, 05/19/09, abnormal, showing spikes in the left anterior region supportive of seizure disorder; Magnetic resonance, clear. 8/14/09 PCP and ER records received DOS 3/28/05 to 7/30

History: None. HPV #3 given 5/14/09, Lot # 1312X, LA. 8/14/09 PCP and ER records received DOS 3/28/05 to 7/30/09. Fever, congested, coughing. Pharyngitis. Allergies - pollen.

Prex Illness:

Prex Vax Illns:

Vaers Id: **353873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	01-Apr-2008		12-Aug-2009	13-Aug-2009	FR	WAES0908USA00401	13-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myoclonic epilepsy

Symptom Text: Information has been received from a health care professional via CSL as part of a business agreement (manufacturer control # 20090804JZ1) concerning a 15 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that the onset of myoclonus was in April 2008. Neurologist suspected that it was unrelated to GARDASIL but rather a case of juvenile myoclonic epilepsy. Upon internal review myoclonic epilepsy was determined to be another important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **353894-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Aug-2008	26-Aug-2008	15	12-Aug-2009	25-Aug-2009	TX		25-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fungal infection, Vaccine positive rechallenge

Symptom Text: Patient developed severe and longlasting yeast infections after first and second dose of Gardasil. Doses were given 2 months apart. Gardasil #1 08/11/2008. Gardasil #2 10/10/2008

Other Meds: N/A

Lab Data: vaginal exam and wet prep

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **353908-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2009	12-Aug-2009	0	12-Aug-2009	24-Aug-2009	IA		25-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF485BA	5	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2920AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0087Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Grand mal convulsion, Incontinence, Nausea

Symptom Text: Patient was sent to the nurses station to receive a Gardasil, Menactra, and Tetanus shot. She received all three, and was asked if she felt okay, replied yes. She found her mom and her mom asked her again if she felt okay, again she stated yes. They made it to the car and the patient started complaining of nausea. As they started driving towards home, they made it about 1/2 block and the mother states that pt started seizing. She explains that she did not pass out, but did have tonic/clonic like seizure and did become incontinent. Mother drove the patient back to our clinic where she was seen again by ARNP.

Other Meds: Vitamin supplements, no prescriptions

Lab Data:

History: none

Prex Illness: vertigo

Prex Vax Illns:

Vaers Id: **353909-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Aug-2009	05-Aug-2009	0	12-Aug-2009	25-Aug-2009	WA		25-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0314Y	2	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHABVB582AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness

Symptom Text: Patient passed out about 5 minutes after receiving both Gardisil #3 and Hep B #2 immunizations. Came to rather quickly after cold compresses were applied to forehead and neck, and was able to walk out of clinic with mother in about 15 minutes after event.

Other Meds:

Lab Data: None.

History: none

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **353910-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Aug-2009	12-Aug-2009	0	12-Aug-2009	24-Aug-2009	IL		24-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF486BA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2819AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Patient experienced vomitting approximately 10 mins after recieving vaccines. Vaccines were administered at approximately 12:30 pm.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **353921-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Jun-2009	02-Jul-2009	7	12-Aug-2009	13-Aug-2009	FR	D0062588A	13-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	XHBVB426CA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NG29050		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Cauda equina syndrome, Hypoaesthesia, Muscular weakness, Nerve root compression, Nerve root lesion, No reaction on previous exposure to drug, Paresis, Urinary hesitation

Symptom Text: This case was reported by a regulatory authority (# DE-PEI-PEI2009016805) and described the occurrence of paresis in a 17-year-old female subject who was vaccinated with ENGERIX B adult, (GlaxoSmithKline). Co-suspect vaccination included GARDASIL. Previous vaccinations with ENGERIX B and GARDASIL were well tolerated. There was no concurrent medical condition. Concurrent medications included birth control. On 25 June 2009 the subject received unspecified dose of ENGERIX B adult (intramuscularly, unknown application site), together with unspecified dose of GARDASIL (intramuscularly, unknown application site). On 2 July 2009, 7 days after vaccination with ENGERIX B adult and GARDASIL, the subject experienced lumbago. On 6 July 2009 the subject experienced aggravated back pain. On 8 July 2009 the subject experienced hypoesthesia and paresis of the right foot. On 12 July 2009 the subject experienced hesitancy with urination. This case was assessed as medically serious by GSK. The subject was treated with ibuprofen from 2 to 6 July 2009. At the time of reporting, on 17 July 2009, hesitancy with urination was improved, hypoesthesia and paresis were unresolved. The outcome of lumbago and back pain was unknown. The reporting physician considered that the events were related to vaccination with ENGERIX B adult, but first of all to vaccination with GARDASIL. The subject visited a neurologist. According to the neurologist's report, the subject experienced discrete weakness of lifting the right foot and toes. Spreading of the toes was slightly aggravated. The subject experienced hypoesthesia of the right forefoot. Electromyography: at renewed repeated sounding in the right Musculus tibialis anterior and right Musculus triceps surae when resting no active denervation at maximal innervation, electroneurographically also at muscular activity. Electromyography derivation from the antagonist: innervation partly noticeable. Nerve conduction speed: right and left Nervus peroneus dist. mot. about 4.0 msec, mot

Other Meds: Birth control

Lab Data: Electromyography: at renewed repeated sounding in the right Musculus tibialis anterior and right Musculus triceps surae when resting no active denervation at maximal innervation, electroneurographically also at muscular activity. Electrom

History:

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354017-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	29-Jun-2009	30-Jul-2009	31	13-Aug-2009	14-Aug-2009	MI	WAES0908USA00799	14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Information has been received from a nurse and the patient's mother concerning a 24 year old female with migraine & depression, no known drug allergies (NKDA) and a history of seizure due to an overdose of WELLBUTRIN which was only one incident couple years ago. Concomitant therapy included LOESTRIN 1/20 and WELLBUTRIN. On 29-JUN-2009 the patient was vaccinated with the first dose of GARDASIL (LOT #658556/1060U). On 30-JUL-2009 she had a seizure. The outcome of the patient was recovered. She sought medical attention and was taken to ER but was not admitted. Upon internal review, seizure was determined to be an other important medical event. No further information is available.

Other Meds: WELLBUTRIN; LOESTRIN

Lab Data: Unknown

History: Convulsion

Prex Illness: Migraine; Depression

Prex Vax Illns:

Vaers Id: **354021-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Jul-2009	27-Jul-2009	0	13-Aug-2009	14-Aug-2009	FR	WAES0908USA01037	14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1882U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Fall, Jaw fracture, No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a gynaecologist concerning a 16 year old female patient who on 27-JUL-2009 was vaccinated IM with the second dose of GARDASIL (lot #: 1882U, batch #: NJ08310) into the upper arm on 27-JUL-2009. 10 to 15 minutes post vaccination, the patient experienced syncope for about 1-2 minutes. She fell down and sustained a mandibular fracture. She was admitted to hospital for monitoring and to exclude concussion. Fracture was treated nonsurgical. She was discharged on 28-JUL-2009. It was reported the first vaccination with GARDASIL given on an unspecified date was well tolerated. Additional information has been requested. Other business partner numbers include E2009-07773.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **354022-1 (S)** **Related reports:** 354022-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Jun-2009	09-Jun-2009	0	13-Aug-2009	14-Aug-2009	TN	WAES0908USA01092	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Adnexa uteri pain, Aspartate aminotransferase increased, Back pain, Chills, Cough, Cystitis, Dehydration, Dizziness, Ear pain, Fatigue, Headache, Lymphocyte count increased, Malaise, Muscle spasms, Myalgia, Nasal congestion, Nausea, Nocturia, Oral contraception, Oropharyngeal pain, Pain, Pelvic inflammatory disease, Pharyngitis, Pyrexia, Ulcer, Urinary tract infection, Uterine cervical pain, Vaginal discharge, Vaginal odour, Viral infection, Vomiting, Weight decreased

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter who was in the remission of rheumatoid arthritis, with allergies to KEFLEX, MORPHINE and Phenergan (manufacturer unknown) and a history of having 2 periods per month. The patient on 09-JUN-2009 was vaccinated with GARDASIL. There was no concomitant medication. Within 30 minutes of the vaccination, the patient experienced fever, chills and vomiting. She was taken to office the next day and she was diagnosed with a bladder infection. She was prescribed antibiotics (unspecified); however, the antibiotics were not taken as the mother was concerned with the side effects affecting the muscles as the daughter was in remission for rheumatoid arthritis. Also, the day prior, the daughter did not show positive for a bladder infection. So the mother did not feel that the daughter had a bladder infection. After 4 days of daily vomiting, her daughter began to feel better. The fever, chills, muscle aches and cramps subsided; however, the vomiting continued to occur occasionally. On 17-JUL-2009, her daughter was taken to the emergency room due to the vomiting. She was discovered to have pelvic inflammatory disease. Tests for gonorrhea and chlamydia were negative. She was given PEPCID and NEXIUM for nausea and treatment of an ulcer which resulted from her vomiting. She was not admitted at this time. By the second week of July, the patient was throwing up a lot. On 21-JUL-2009, the mother took her daughter to the hospital. The patient was having headaches and throwing up at least once everyday. The patient was admitted and treated for dehydration from vomiting. (She also could not take the prescribed antibiotics for PID due to the vomiting). In the hospital, the patient was given intravenous antibiotics for 4 days for the abdominal pain. Various labs and diagnostic testing were done. Upper GI, CAT scan of the liver, kidneys and appendix were all normal. The patient was discharged with antibiotics (unspecified) for 10 days. She was scheduled for a sco

Other Meds: None

Lab Data: Computed axial, 07/21/09, liver: normal; Upper GI series X-ray, 07/21/09, normal; Computed axial, 07/21/09, kidneys: normal; Computed axial, 07/21/09, appendix: normal; Neisseria gonorrhoeae, 07/17/09, negative; Serum Chlamydia, 07/17/09, n

History: Pregnancy 9/25/09 Received medical records w/PMH: JRA. Allergy: keflex, morphine. 10/5/09 Hospital records, DC summary, DOS 7/22/09 to 7/25/09.Rheumatoid arthritis, ovarian cyst. Staph infection of finger. T&A. Keflex and morphine allergies. 10/21/09 GI Consultations received for Dates of Service 8/17/09 and 9/11/09. PMH: Rheumatoid arthritis, keflex and morphine allergies.

Prex Illness: Rheumatoid arthritis; Allergic reaction to antibiotics; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **354022-2 (S)** **Related reports:** 354022-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Jun-2009	09-Jun-2009	0	13-Aug-2009	18-Aug-2009	TN		04-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Chills, Headache, Malaise, Mood swings, Muscle spasms, Myalgia, Nausea, Pelvic inflammatory disease, Pyrexia, Vomiting

Symptom Text: My daughter received the first GARDASIL Vaccine on June 9, 2009. Within 30 minutes she became ill with nausea, vomiting, fever, chills, headaches and severe muscle aches. I phoned the doctor they stated that she may have picked up a bug at the office the day before. Long story short, she recovered from the fever, chills and muscle cramps after 4 days but has continued vomiting, having stomach cramps and headaches and was hospitalized from July 21st through the 24th in the hospital. She had been to the emergency room on July 17th and 18th where we reside, and she was diagnosed with Pelvic Inflammatory Disease, PID. They treated her vomiting as an ulcer - guess work by prescribing PEPSID, which did not work, and said that the PID had to come from a sexually transmitted disease, but those test returned negative. At the hospital she was treated for the infection by I.V. antibiotics, since she was unable to hold anything down. She was tested for multiple things that would possibly explain the vomiting, but nothing showed up. I later found out on your site that PID, vomiting and headaches were all rare side effects of the GARDASIL Vaccine. My question is, because not one doctor was even aware of the possible side effects, so they do not have a clue as to when these side effects will subside or go away. She is no longer vomiting after every meal, yet she still vomits at least once a day and suffers from headaches and stomach aches. I am a single mom and the work that I had to miss has created a huge burden for me. But more than anything, my daughter and I would love to have an answer of where the light at the end of the tunnel may be! Follow-up:I would like to update my daughter's condition. Her report number is 354022. It has now been seven months since her one and only shot of GARDASIL and she continues to vomit every day. Also, I was looking at her VAERS report and it states that she has a preexisting condition of pregnancy. Please remove that from her report, as she has never been pregnant. Very irregular periods.

Other Meds:

Lab Data: 7/19/09: Pelvic Ultra Sound, Pelvic Exam, X-ray of gallbladder and kidneys, lab work...ie BMP, CBC, PREGNANCY HCG, SED RATE, and UA Void. Also checked for Gonorrhea and Chlamydia/GC DNA, both negative, From 7/21 through 7/23/2009 Upper G.I.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **354023-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		13-Aug-2009	14-Aug-2009	--	WAES0908USA01451	14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Carcinoma in situ

Symptom Text: Information has been received from a physician concerning a 22 year old female patient who was vaccinated with the series of GARDASIL, 0.5 ml and developed "CIS 2" after completing the vaccination series. No information regarding the time frame for the first, second and third dose of GARDASIL. No lot number was provided. Unspecified medical attention had been sought. Upon internal review, "CIS 2" was determined to be an other important medical event. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **354024-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Apr-2008	01-Feb-2009	295	13-Aug-2009	14-Aug-2009	FR	WAES0908USA01514	14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Colitis ulcerative

Symptom Text: Information has been received from a Health Authority (ref no: 20467369), via an agency as part of a business agreement, concerning a 17 year old female patient who on 12-APR-2008 was vaccinated intramuscularly with the third dose of GARDASIL (site and batch number not reported). Concomitant therapy included OVRANETTE. Details of the patient's medical history have not been reported. The patient weighted 50 kg. The patient received three doses of GARDASIL (batch number not reported) between 13-OCT-2007 and 12-APR-2008. On 01-FEB-2009, eight months after the last dose, a colonoscopy was performed and the patient was diagnosed of severe distal ulcerative colitis. This was not responsive to treatment with steroid or balsalazide. The patient is now receiving treatment with azathioprine. The patient was not recovered. Both the reporter and the Health Authority considered this to be a serious due to disability and incapacity. No more information is available, this case is closed. Other business partner numbers include: E2009-07840.

Other Meds: OVRANETTE

Lab Data: Colonoscopy, 01Feb09, severe distal ulcerative colitis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **354025-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
31.0	F	14-Apr-2009	15-Apr-2009	1	13-Aug-2009	14-Aug-2009	FR	WAES0908USA01516	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Inappropriate schedule of drug administration, Nuclear magnetic resonance imaging brain normal

Symptom Text: Information has been received from the Foreign Health Authority, reference number ES-AGEMED-825347132, concerning a 31 year old female who on 14-APR-2009 was vaccinated with a dose of GARDASIL. 24 hours after vaccination, on 15-APR-2009 the patient presented with a left hemihypoesthesia which she recovered from on the 16-APR-2009. In the Health Authority's report, hypoesthesia has been coded. On 2009 (exact date not reported) a cranial MRI was performed along with a carotid sonogram and a coagulation test to rule out a possible systemic illness, results were all normal. Case reported serious by the Foreign Health Authorities with other medically important condition as criteria. Other business partner number included E200907841. Case is closed.

Other Meds: Unknown

Lab Data: carotid artery ultrasound, ??09, normal; magnetic resonance imaging, ??09, normal; activated coagulation time, ??09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **354026-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	05-Mar-2008	30-Aug-2008	178	13-Aug-2009	14-Aug-2009	FR	WAES0908USA01519	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Headache, Pyrexia

Symptom Text: Information has been received from Health Authorities concerning a 20 year old female who on 05-MAR-2008 was vaccinated with her 2nd dose of GARDASIL (batch# and site of administration not reported) IM. Concomitant medication included NOVORAPID and LANTUS. Approximately six months post vaccination, on 30-AUG-2008 the patient experienced persistent non-recurrent frontal headache for one year and fever for 15 days. In July 2009 the patient presented increased transaminases values. Analysis and serodiagnosis were performed to rule out infectious disease and found increased transaminases and increased serodiagnosis rate. Corrective treatment with antalgic and antiemetic drugs was ineffective. At the time of reporting, the patient was not recovered. Final outcome is not reported. Case is closed. Frontal headache, fever and transaminases increased were considered to be disabling. Other business partner numbers included E2009-07849.

Other Meds: LANTUS; NOVORAPID

Lab Data: diagnostic laboratory test, ??Jul09, no infectious disease, increased transaminases, increased serodiagnosis rate

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **354029-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2009	Unknown		13-Aug-2009	14-Aug-2009	FR	WAES0908USA01532	28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal distension, Alopecia, Anorexia, Autoantibody negative, Blood bilirubin increased, Blood calcium normal, Blood cholesterol normal, Blood electrolytes normal, Blood iron normal, Blood test, Blood urea normal, C-reactive protein normal, Constipation, Dizziness, Feeling cold, Feeling hot, Full blood count normal, Hot flush, Hypoaesthesia, Liver function test normal, Malaise, No reaction on previous exposure to drug, Nuclear magnetic resonance imaging, Paraesthesia, Thyroid function test normal, Transferrin saturation increased, Weight decreased

Symptom Text: This case was initially reported to foreign agency by a health care professional on 31-JUL-2009. This case concerns a female patient (age not reported). Details of the patient's medical history and concomitant medication have not been reported. The patient received the first dose of GARDASIL on January-09 without any problems. The patient's sister received the GARDASIL at the same time without any problem. On an unspecified date, but when the dose was due, the patient received the second dose of GARDASIL (batch#, lot#, route and site not reported). On an unspecified date but following the second dose, the patient became very ill for a number of months with hair loss, which was coming out in lumps, weight loss, numbness and tingling in her arm, dizziness, loss of appetite, feeling full and bloated, cold and constipated and hot and cold flushes. The patient underwent a magnetic resonance scan (MRI) and unspecified blood tests (results not reported). The patient outcome is unknown. The patient and her sister refused vaccination with the third dose of GARDASIL. Upon internal review this case has been upgraded to serious due to the events of dizziness, numbness and tingling. Other business partner number included: E200907764. No further information is available. This information was previously reported in WAES# 0908USA00660. This report was created in order to capture the correct country source name (previously captured as a different country in WAES#0908USA00660). It was determined that WAES#0908USA00660 was previously sent to the FDA with an incorrect country source. Therefore, WAES#0908USA00660 was deleted from our files and the new report created for this case is WAES#0908USA01532. "WAES0908USA00660 was previously submitted to the FDA on 07-AUG-2009." This is a follow-up report(s) previously submitted on 12Aug09; 25Aug09; 26Aug09. This case was initially reported to SPMSD UK by a health care professional on 31-JUL-2009. This case concerns a female patient (age not reported). Details of the patient's medical histor

Other Meds: Unknown

Lab Data: arterial blood 02 saturation 08May09: 56

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354032-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		13-Aug-2009	14-Aug-2009	--	WAES0908USA01533	14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Carcinoma in situ

Symptom Text: Information has been received from a physician concerning a 23 year old female patient who was vaccinated with the series of GARDASIL, 0.5 ml and developed "CIS 2" after completing the vaccination series. No information regarding the time frame for the first, second and third dose of GARDASIL. No lot number was provided. Unspecified medical attention had been sought. Upon internal review, "CIS 2" was determined to be an other important medical event. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **354037-1 (S)** **Related reports:** 354037-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Aug-2009	04-Aug-2009	0	13-Aug-2009	18-Aug-2009	NJ		24-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB249AD	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0087Y	0	Left arm	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Dyspnoea, Heart rate decreased, Hyperhidrosis, Loss of consciousness, Nausea, Pallor

Symptom Text: Vaccine was administered, patient became dizzy 30 seconds after shot. Patient was pale, diaphoretic & nauseous. Symptoms lasted about 45 minutes. BP dropped to 90/50 & pulse to 50/min. 8/20/09 PCP note received DOS 8/4/09. After shots pt became naseated, pale, diaphoretic, dizzy and had difficulty breathing. BP dropped to 90/50 and pulse into the 50's. Sx lasted ~45 minutes with return to baseline. Vax record states pt "passed out".

Other Meds:

Lab Data:

History: 8/20/09 PCP note received DOS 8/4/09 Never experienced these symptoms with previous shots.

Prex Illness:

Prex Vax Illns:

Vaers Id: **354037-2 (S)** **Related reports:** 354037-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Aug-2009	04-Aug-2009	0	29-Jan-2010	01-Feb-2010	--	WAES0909USA01653	01-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB249AD	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0087Y	0	Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Dizziness, Dyspnoea, Hyperhidrosis, Loss of consciousness, Nausea, No reaction on previous exposure to drug, Pallor

Symptom Text: This report was identified from a line listing obtained on request by the Company the FDA under the Freedom of Information Act. On 04-Aug-2009 a 16 year old female was vaccinated in the left arm with a first dose of GARDASIL (Lot #662518/0087Y). On the same day she was also vaccinated in the left arm with a first dose of HAVRIX (Lot #AHAVB249AD). Patient became dizzy 30 seconds after the shot. Patient was pale, diaphoretic and nauseous. Symptoms lasted about 45 minutes. Her blood pressure dropped to 90/50 and pulse to 50/minutes. On 20-Aug-2009 the primary care physician not was received (date of service 04-Aug-2009). It was reported that after the shots, patient became nauseated, pale, diaphoretic, dizzy and had difficulty breathing. Blood pressure dropped to 90/50 and pulse into the 50's. The symptoms lasted about 45 minutes with return to baseline. Vaccine records stated patient "passed out." According to the PCP not received on 20-Aug-2009 (date of service 04-Aug-2009), the patient never experienced these symptoms with previous shots. The listing indicated that one or more of the events was considered to be immediately life-threatening. No further information is available. The original reporting source was not provided. The VAERS ID # is 354037-1. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center for Biologics Evaluation and Research and was released.

Other Meds:

Lab Data: blood pressure, 08/04/09, 90/50 puls; total heartbeat count, 08/04/09, 50's/min

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354039-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		13-Aug-2009	25-Aug-2009	UT		22-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	2582	5	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	4290688	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	26440312Y	1	Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	0584Y	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness transient, Dysstasia, Hyperhidrosis, Immediate post-injection reaction, Loss of consciousness, Mydriasis, Pallor, Unresponsive to stimuli

Symptom Text: Approximately 20 seconds after the GARDASIL with no warning she passed out and became unresponsive for 10 seconds. She was very pale, diaphoretic and had a heart rate of about 64. When she came too she was unable to stand and had fully dilated pupils and so could not see. I managed to get her to a room with a table and lay her down. She gradually became fully responsive but had dilated pupils for about 7 minutes from the start of the reaction. Being concerned about anaphylaxis I called 911 while she was not fully responsive, they came and checked vitals, BP 104/68, glucose 94. At no time was her breathing compromised. This whole episode lasted about 25 minutes, after which she fully recovered.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **354041-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Oct-2007	28-Jul-2009	665	13-Aug-2009	25-Aug-2009	PA		25-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1501F	1	Left arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B006AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB266BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pertussis, Polymerase chain reaction

Symptom Text: Pt acquired PCR positive for pertussis 7/28/2009

Other Meds:

Lab Data:

History: asthma, migraines, reflex neurovascular dystrophy, chiari malformation

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354043-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	02-Jul-2008	23-Jul-2009	386	13-Aug-2009	25-Aug-2009	PA		25-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1757U	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2632AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024CA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284CA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pertussis, Polymerase chain reaction

Symptom Text: Pt developed pertussis (PCR positive) on 7/23/2009)

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **354052-1** **Related reports:** 354052-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	13-Aug-2007	01-Nov-2007	80	13-Aug-2009	25-Aug-2009	VA		26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Attention deficit/hyperactivity disorder, Convulsion

Symptom Text: Patient reported to us o10/22/09: She had a seizure 2 months after 2nd GARDASIL Injection Neurology Consultations received for dates of service 9/8/08 to 3/9/09. Dx: Seizures disorder. Assessment: Developed 2 loss of consciousness episodes with tongue biting in 11/07 and 12/07. She started on Topamax, but found that it caused side effects, so was switched to Depakote, on which she also had side effects. She is now on Keppra and has remained seizure free since the initiation of antiepileptic drugs. Noted memory problems on Keppra and was started on Adderall for ADD with good results. She developed anxiety for which she was prescribed alprazolam.

Other Meds: YASMIN; birth control pills.

Lab Data: 2 - MRI's, 2 - EEG's. 2 EKG's, 24 hour EEG ->; All were negative. Neurology Consultations received for dates of service 9/8/08 to 3/9/09. Labs and Diagnostics: MRI of the brain-normal, 24 hour EEG-normal.

History: None. Neurology Consultations received for dates of service 9/8/08 to 3/9/09. PMH: ADD, breast augmentation.\n 8/5/09.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **354052-2** **Related reports:** 354052-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	13-Aug-2007	01-Nov-2007	80	19-Aug-2009	20-Aug-2009	--	WAES0908USA02226	26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse concerning a 20 year old female who on 13-AUG-2007 was vaccinated intramuscularly on her left deltoid with the second dose of GARDASIL (Lot # 658222/0927U). Concomitant therapy included YASMIN. On 01-NOV-2007 two months after her second vaccination the patient experienced a seizure. The patient sought medical attention and went to an unspecified emergency room. The patient was prescribed TOPAMAX, DEPAKOTE, KEPPRA in the beginning of November 2007. The patient underwent two magnetic resonance imaging (MRI), two electroencephalography (EEG), two electrocardiogram (EKG) and a 24 hour EEG which were all negative. Unknown if the third dose of GARDASIL was given at the office as 05-AUG-2009. The patient recovered from seizure. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: YASMIN

Lab Data: Electroencephalography, 11/??/07, negative; Magnetic resonance, 11/??/07, negative; Electrocardiogram, 11/??/07, negative; Electroencephalography, 11/??/07, negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **354057-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Jul-2009	23-Jul-2009	0	13-Aug-2009	25-Aug-2009	FL		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1423X	1	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336AA	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Nausea

Symptom Text: Patient experienced dizziness and nausea appox: 5 minutes after vaccination. Patient was placed on back w/legs raised for 15 minutes. Nausea and dizziness and nausea resolved with no further action.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **354062-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-May-2009	22-May-2009	0	13-Aug-2009	14-Aug-2009	FR	B0587844A	14-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ25950	0	Unknown	Subcutaneously	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB115AK	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Decreased activity, Hypotonia, Syncope

Symptom Text: This case was reported by a regulatory authority (# ES-AGEMED-031435340) and described the occurrence of syncope in a 12-year-old female subject who was vaccinated with TWINRIX pediatric (GlaxoSmithKline), GARDASIL (non-gsk). On 22 May 2009, the subject received 2nd dose of TWINRIX pediatric (subcutaneous, unknown injection site), 1st dose of GARDASIL (subcutaneous, unknown injection site). On 22 May 2009, less than one day after vaccination with GARDASIL and TWINRIX pediatric, the subject experienced syncope with hypotonia and hypoactive. The regulatory authority reported that the events were clinically significant (or requiring intervention). On 22 May 2009, the events were resolved. The regulatory authority reported that the events were probably related to vaccination with TWINRIX pediatric and GARDASIL. No further information could be obtained as the regulatory authority has provided all the available information. This case has therefore been closed.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354084-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	U	10-Aug-2009	10-Aug-2009	0	13-Aug-2009	25-Aug-2009	PA		25-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Headache

Symptom Text: pt had headace and stomache slef resolving after 24 hours

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **354096-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Aug-2009	11-Aug-2009	0	13-Aug-2009	25-Aug-2009	FL		25-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2928AB		Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0497X		Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0312X		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Eye movement disorder, Immediate post-injection reaction, Nausea, Syncope

Symptom Text: Patient became very dizzy, nauseous immediately after vaccines given, eyes fluttering back. Her syncope lasted >15 min; EMS called transported to ER. She was fasting & she had blood drawn prior to vaccines.

Other Meds: None

Lab Data: ALCUV glucose -80

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **354114-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	27-Jul-2007	12-Jan-2009	535	13-Aug-2009	25-Aug-2009	FL		25-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Autoimmune disorder, Idiopathic thrombocytopenic purpura, Platelet count decreased

Symptom Text: Blood work was done as a routine physical one year after vaccine was distributed and the patients blood platelet count was at a low of 90 (normal range 140-400) Primary physician suggested that patient see a hemotologist, over the last year 2008-2009 patient has undergone routine bloodwork 01-09, 03-09, 05-09, and platelet count was still low, then Hemotologist had patient do a bone marrow biopsy to see if maybe her marrow wasnt producing enough platelets, biopsy showed that marrow was producing a healthy count of platelets, so after much blood work and evaluation, patient now has an auto-immune disease called ITP where her immune system is killing off her platelets leaving her with a low range of platelets, prior to the vaccination blood work shows normal range of platelet counts.

Other Meds:

Lab Data: Blood work done every 1-4 months, as well as a bone marrow biopsy

History: mitro-valve regurgitation

Prex Illness:

Prex Vax Illns:

Vaers Id: **354117-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	13-Aug-2009	13-Aug-2009	0	13-Aug-2009	25-Aug-2009	TX		25-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	9724309		Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB244AD		Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0100Y		Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2925AA		Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3246BA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Syncope

Symptom Text: Received the following vaccinations today (at approximately 1545)including Tdap, MCV4, HepA, Varivax and HPV. The patient stood up from exam table about 4 minutes after the last shot (HPV), then fainted, fell to ground and experienced LOC for few seconds. After 15 minutes further observation, the patient was fine and left for home.

Other Meds: Sertraline 25 mg, Singulair 5 mg

Lab Data: none

History: seasonal allergic rhinitis, in foster care since 2/6/09

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354126-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	13-Jul-2009	13-Jul-2009	0	13-Aug-2009	25-Aug-2009	WI		21-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1315Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Loss of consciousness, Muscle rigidity

Symptom Text: Loc for a few seconds body stiffened face flushed.

Other Meds: Multivitamins

Lab Data: Vital signs stable

History: Previous Vaso-vagal and blood draw

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354128-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-Aug-2009	13-Aug-2009	0	13-Aug-2009	25-Aug-2009	WI		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB329AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor

Symptom Text: Pt felt lightheaded and was pale.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354136-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	29-Jul-2009	29-Jul-2009	0	13-Aug-2009	25-Aug-2009	WV	WV0906	25-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	UF460BA	0	Right arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB672BA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2689AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Immediate post-injection reaction, Syncope

Symptom Text: Immediately following HPV injection, pt. experienced syncope. Pt. was seated, fell to the to the right side, and struck the right side of her head on the floor. An ammonia capsule was provided for pt. inhalation. Pt. awakened after app. 60 seconds. Carefully moved to sitting position. Ice applied to Rt. head. Pt. alert and oriented. No visible injuries.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354193-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Jun-2009	24-Jun-2009	2	14-Aug-2009	17-Aug-2009	FR	WAES0908USA01520	17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Encephalitis, Headache, Musculoskeletal pain, Neck pain

Symptom Text: Case reported by Health Authority (case n. 102085) through authority (local case n. IT334/09). Initial report received on 06-AUG-2009. An 11-year-old female was vaccinated on 22-JUN-2009 with a dose of GARDASIL (batch n., route and site of administration not reported). On 24-JUN-2009, 3 days after vaccination, the patient experienced meningoencephalitis, probably of viral etiology without any pathogen isolated and with progressive evolution. Since 21-JUN-2009, the patient presented headache and cervical pain during treatment with TACHIPIPINA and ibuprofen for right shoulder post trauma pain since 5 days. All the treatment were withdrawn, sedation and mechanical ventilation. DEPAKINE IV, acyclovir IV, ROCEPHINE, ampicillin IV, dexamethasone, omeprazole IV. Final outcome is not reported. Case is closed. Health Authority (HA) considered paracetamol and ibuprofen as suspect drugs and coded the reactions meningoencephalitis and headache. Other business partner numbers include: E2009-07851. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **354194-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	26-Jun-2009	10-Jul-2009	14	14-Aug-2009	17-Aug-2009	--	WAES0908USA01558	04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	661954/1131X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician's assistant concerning a 26 year old female with no past history of seizure and no drug allergies, who on 26-JUN-2009 was vaccinated with her 1st dose of GARDASIL, 0.5ml. There was no concomitant medication. Subsequently, two weeks post vaccination the patient had seizure at home on approximately 10-JUL-2009. There were no labs and diagnostic tests performed. The patient was seen at a follow up visit. At the time of the report, the patient's status was recovered. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354195-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		14-Aug-2009	17-Aug-2009	--	WAES0908USA01559	17-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Headache, Intracranial aneurysm

Symptom Text: Information has been received from a licensed visiting nurse concerning a female who was vaccinated with a dose of GARDASIL (dose, route and lot# not reported). The nurse reported that the patient developed a severe headache after receiving GARDASIL. The patient was first seen by the school nurse, who advised evaluation in an emergency room or the physician's office. The patient was seen the next day at the physician's office and then sent to an unspecified emergency room and admitted to this hospital. The patient was diagnosed with a brain aneurysm. On an unspecified date, the patient recovered from brain aneurysm. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **354245-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Aug-2007	09-Aug-2007	0	14-Aug-2009	25-Aug-2009	MI		26-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	0	Left leg	Unknown	
	VARCEL	MERCK & CO. INC.	0848U	1	Right leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Severe headache 2-3d after vaccine and erythema, swelling, tenderness at left leg injection site.

Other Meds: None

Lab Data: None

History: Healthy Child

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354293-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	14-Aug-2009	14-Aug-2009	0	14-Aug-2009	25-Aug-2009	TX		25-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	MO491Y	2	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	M1497X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Pallor, Syncope

Symptom Text: PT. RECEIVED HPV AND VARICELLA IMMUNIZATIONS. UPON LEAVING, WHILE WALKING IN HALLWAY, MOTHER STATES THAT PT. LOOKED PALE, FAINTING AND HITTING HEAD AGANIST WALL. PT. TAKEN TO EXAM TABLE IN CLINIC-VITAL SIGNS B/P118/68, P-68,R-16,ELEVATED LEGS WHILE PT. LYING DOWN, RESPONDED TO TIME, PLACE, DAY, PURPOSE OF VISIT. CHECKED FOR ANY BRUISING, OPEN AREAS,LUMPS, BLEEDING, NON VISIBLE. STATED COULD SEE ME. MONITORED FOR 20 MINUTES, NO OTHER S/S NOTED. MOTHER STATED THIS EPISODE OF FAINTING OCCURED WHEN 5YRS. OLD DURING A FINGERSTICK. MOTHER STATED THAT THIS TIME, PT. "WORKED HERSELF UP" OVER "SHOT". ADVISED MOTHER (SANTOS ADELA BARRAGAN)TO TAKE PT. TO ER FOR FURTHUR EVAL, HOWEVER, STATED PT. WOULD BE FINE AND SHE WOULD TAKE HER HOME FOR DINNER. IF ANY OTHER S/S OCCURRED, SHE WOULD THEN TAKE HER TO ER. AT INITIAL ASSESSMENT MOTHER DID NOT MENTION PREVIOUS EPISODE OF FAINTING-PT. DID HAVE LUNCH.

Other Meds: NONE

Lab Data: NONE

History: NONE-REPORTED BY MOTHER

Prex Illness: MOTHER STATES NONE

Prex Vax Illns: NONE~ ()~NULL~~In Patient|NONE~ ()~NULL~~In Sibling1|NONE~ ()~NULL~~In Sibling2

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354297-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	06-Aug-2009	Unknown		14-Aug-2009	24-Aug-2009	NJ		24-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness, Syncope

Symptom Text: After receiving gaurdicil, lauren fainted while walking out of the doctors office. Completely blacked out, head hit the floor, fainted. Now (I am an RN) after reading about girls fainting as a side effect, I'm very concerned about the doctors and nurses being warned to keep the person sitting in a chair for a period of time, before they leave the doctors office. What if she had fainted in the car while she was driving?

Other Meds: lexapro

Lab Data:

History: allergy sulfa

Prex Illness: no

Prex Vax Illns:

Vaers Id: 354301-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Nov-2007	20-Nov-2007	19	16-Aug-2009	25-Aug-2009	UT		31-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	12100	3	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Abdominal pain upper, Activities of daily living impaired, Arthralgia, Cholecystectomy, Constipation, Contusion, Cough, Dehydration, Diarrhoea, Dizziness, Dyspepsia, Flank pain, Headache, Inappropriate schedule of drug administration, Irritable bowel syndrome, Laparoscopic surgery, Malaise, Musculoskeletal pain, Nausea, Pelvic inflammatory disease, Pelvic pain, Syncope, Urinary tract infection, Urticaria, Viral upper respiratory tract infection, Vision blurred, Wheezing

Symptom Text: I had the last shot in early November 07, been sick sense. November 20 Fainted in store multiple times. Perfectly normal healthy happy teenager before. Have severe pain in stoamche area, had galbladder removed, pain still occured. Have an all over sick feeling. Some days I cant get out of bed. Had to quit going to highscool after the shot. Have serious stomache and digestive problems. Take medication for IBS which occured after the third Gardail shot. Been to Emergency room over 10 times in the last two years due to ilness and severe pain. 11/2/09: Vaccine record received, VAERS updated. 11/3/09: Outpatient Records received for dates of service 11/26/07 to 8/10/09. Dx: Pelvic pain Assessment: Long hx. of RUQ and RLQ abdominal pain. Underwent cholecystectomy with resolution of RUQ pain, but continued to have persistent RLQ pain. Has alternating constipation and diarrhea as well and headaches, blurred vision, dizzy spells and occasional nausea. Pt. had risk factors for PID so was treated with Rocephin and doxycycline with no relief of sx. She underwent a diagnostic laparoscopy which was normal. She is medicated with Lortab for when the pain is most severe. Her sx. continue. ICD 9 Codes: 724.2, 789.01, 789.03. 11/13/09 ER recs received for dates 11/20/07 to 6/20/09. DX: viral URI. Presenting SX: cough, nausea, wheezing, abdominal pain x2-3 days. Assessment: WNL.ER visit on 10/25/09 for c/o assault. DX: strain of wrist muscles, shoulder strain, contusion of chest. ER visit 6/2/08 c/o stomach pain, diarrhea. DX: UTI, acute abdominal pain. UA(+)WBC. ER visit on 12/29/07 c/o f/u abdominal pain LUQ pain, epigastric abdominal pain.DX: abdominal pain of undeterm etiology. ER visit 12/15/07 DX:postmononucleosis syndrome, dehydration, presyncope. Chief c/o vomiting and side pain. Pt. c/o LUQ pain. Pt states have had many episodes off and on. Also c/o dizziness, lightheadedness. PMH: dx w/ mononucleosis weeks prior. US, bloodwork, UA, WNL. ER visit 11/20/07 DX: h/o syncopal episodes, dizziness and nau

Other Meds: None at the time of vaccination.

Lab Data: IBS,post dramatic mono syndrome, Anxiety. 11/3/09: Outpatient Records received for dates of service 11/26/07 to 8/10/09. Labs and Diagnostics: MRI of Brain-Negative. Colonoscopy-Thickened mucosal folds in distal ileum. Most likely som

History: none. 11/3/09: Outpatient Records received for dates of service 11/26/07 to 8/10/09. PMH: IBS, Depression, Anxiety, GERD, ADHD, choleystectomy, tonsilectomy, adenoidectomy, UTI.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **354303-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	17-Mar-2008	17-Mar-2008	0	16-Aug-2009	26-Aug-2009	MN		02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	02825AA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Alopecia, Amenorrhoea, Arthralgia, Asthenia, Back pain, Body temperature decreased, Constipation, Diarrhoea, Dizziness, Dyspepsia, Emotional distress, Eye pruritus, Fatigue, Food allergy, Fungus stool identified, Gastrointestinal pain, Gastrooesophageal reflux disease, Genital discharge, Headache, Hormone level abnormal, Hypoaesthesia, Hypotonia, Immediate post-injection reaction, Influenza like illness, Irritability, Menstrual disorder, Menstruation irregular, Myodesopsia, Neurological symptom, Oesophageal disorder, Pain in extremity, Palpitations, Paraesthesia, Parasite stool test positive, Pyrexia, Sleep disorder, Urticaria, Vaginal discharge, Vaginal odour, Vaginitis bacterial, Vulvovaginal discomfort, Weight decreased

Symptom Text: Within one week of receiving the first shot (10/24/2007), I experienced flu-like symptoms, fever, and such severe vaginal discomfort that I went to the emergency room. I was diagnosed with bacterial vaginosis. It cleared up, but my health felt off - worse digestion, I started getting heartburn, feeling fatigue, started seeing floaters in my vision and getting terrible headaches, and my menstrual cycle started becoming more irregular. I had always been like clockwork. I started losing weight, which was unusual, as I had always been overweight and had a hard time losing weight. I began feeling more and more irritable, but made no connections to the Gardasil shot. In March, immediately after receiving the second vaccine (3/17/08), my arm hurt terribly, I felt lightheaded, woozy, and had hives appear. Within 1 week, I started experiencing vaginal irritation again, fever, and had flu like symptoms. Over the course of the next month, I started to feel such severe fatigue, stomach aches, and uncontrollable diarrhea, that I went to my doctor. She told me I probably just had acid reflux. Two days later, I experience debilitating stomach pain, which lasted for nearly 1 month. I had an endoscopy, a CT scan, allergy tests, and blood work for thyroid disorders and other imbalances, all of which have come back reasonably normal and regular for my body and system. I did have some esophageal damage from acid reflux, and was put on Prevacid. Receiving no answers from the clinic, I cut out gluten, corn, soy, dairy, eggs, caffeine, alcohol, yeasts, and sugar from my diet and started working with an acupuncturist and naturopath. Stool sampling showed signs of Candida Yeast overgrowth in my intestines and parasites, which I am combating naturally with help from my naturopath, and managed to eliminate with diets and supplements after 9 months of treatment. I a got off the Prevacid successfully with her help, and am starting to feel stronger. All total, after the vaccines, I experienced extreme weight loss (50 pounds), hair loss, fa

Other Meds: daily multivitamin

Lab Data: Endoscopy, CT Scan, MRI, Transvaginal ultrasound, IgG and IgE allergy testing, thyroid tests, blood lipids, metabolic tests, hemogram and platelets, hepatic battery, FSH, TSH, estradiol, prolactin, progesterone, free testosterone, Candida A

History: none PMH: smoker, nut allergy.

Prex Illness: none

Prex Vax Illns: fatigue, menstrual irregularities, digestive issues, emotional issues~HPV (Gardasil)~1~25.30~Patient

Vaers Id: **354318-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	10-Oct-2006	01-Dec-2006	52	14-Aug-2009	26-Aug-2009	MI		28-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0698F	0	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Arthralgia, Back pain, Breath odour, Eructation, Fall, Joint injury, Joint range of motion decreased, Juvenile arthritis, Oedema peripheral, Osteomyelitis, Osteomyelitis chronic, Osteosclerosis, Otitis media, Pain in jaw, Patellofemoral pain syndrome, Spinal fracture, Stress, Swelling face, Synovial cyst, Synovial disorder, Vomiting

Symptom Text: Mom did Reading on GARDSIL and thinks childs Medical problems may be related to GARDASIL. Last GARDASIL 4-16-07. Back pain started Dec-2006, FX Vertebrae - Dec 06, Jaw pain July 07, FX jaw - Sept 07; GARDASIL #1 - 10-10-06, #2 - 12-19-06, #3 - 4-16-07. Dx with JRA spring of 09. Seeing Rheumatologist. Has been Tx for multi focal osteomyelitis. 8/19/09 PCP Medical records received DOS 10/10/06 to 4/16/07. Patient 'gets burps that smell like rotten eggs', then stomach cramps, vomiting when stressed. Abdominal pain. 9/24/09 Infection Disease Consultation medical records received DOS 3/10/08 to 11/27/08. Assessment: Ganglion Cyst Right Hand. Proliferative Periostitis Mandible and L-4 Vertebral Body. Chronic Osteomyelitis of Garre. Patient presents with history of right sided mandibular pain preceeded by use of braces and orthodontic manipulation. Facial assymetry with swelling area of right mandible. After several weeks of no symptoms, new onset right sided jaw pain and swelling. Lump/swelling on back on hand. Back pain. 9/25/09 Rheumatology consult received DOS 2/12/09 to 5/28/09. Assessment: No unifying diagnosis. Chronic recurrent multifocal osteomyelitis. Patellofemoral syndrome. Ganglion cyst - wrist. Back pain. Sledding injury resulting in L4 vertebral Fx dx'd several months later (May 2007) by MRI. Wakes up in morning with severe pain in wrists with limited range of motion. Synovial thickening wrists. Knee pain. Jaw pain. Mandible, fibrous dysplasia. Vertebral body sclerosis. Fell off bicycle and injured knee. Otitis media. Marked improvement with naprosyn.

Other Meds:

Lab Data: 9/15/09 LABS and DIAGNOSTICS received. Oral Pathology Report DOS 2/13/08 - Biopsy Mandible right side - abnormal, benign fibro-osseous lesion, fibrous dysplasia. Oral Pathology Report DOS 6/04/08 - Biopsy Mandible right side - abnormal, pr

History: Reactive Airway disease, possible Asthma. 9/24/09 Infection Disease Consultation medical records received DOS 3/10/08 to 11/27/08. Fall with bruise to right side of face at age 5 yrs.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **354342-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Jul-2009	27-Jul-2009	0	17-Aug-2009	18-Aug-2009	--	WAES0908USA00788	18-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Pallor, Shock

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female who was vaccinated with the "first dose" of GARDASIL (injection, lot# not reported) in the "last week" (approximately 27-JUL-2009). Concomitant therapy included MENACTRA. The nurse stated that the patient received her first dose of GARDASIL and "2 minutes later the patient felt nauseated and she turned white, her lips were white". The nurse added that the patient looked like she maybe going into shock at that time. The nurse took blood pressure and checked her heart rate which were fine and they had the patient lie down for 5 to 10 minutes and then she started to feel better. The patient fully recovered after 20 to 30 minutes. The patient was given water and grapes. Upon internal review, shock was determined to be an other important medical events. Additional information has been requested.

Other Meds:

Lab Data: blood pressure, 07/27?/09, fine; diagnostic laboratory, 07/27?/09, heart rate: fine

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **354343-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Dec-2006	15-Jan-2007	26	17-Aug-2009	18-Aug-2009	--	WAES0908USA00793	18-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Abdominal tenderness, Crying, Diarrhoea, Headache, Heart rate increased, Hyperhidrosis, Hypertension, Impaired gastric emptying, Palpitations, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter with no pertinent medical history and no known drug allergies who in "August/September 2006", was vaccinated with the first 0.5ml dose of GARDASIL (injection, lot# not reported). There was no concomitant medication. The consumer reported that in "mid January 2007", her daughter experienced diarrhea, vomiting and she was unable to keep food in her stomach after getting second dose of GARDASIL in November/December 2006. The patient was hospitalized end of February 2007 and was diagnosed with gastroparesis by physician at the hospital. The patient was discharged on 07-MAR-2007. She received the third dose of GARDASIL in April/May 2007. Lot# was not provided. The patient was recovered but she would get periodic gastroparesis it depended on what she ate. On unspecified day, a stomach emptying scan test and numerous other tests were performed, and the results were unknown. Follow up information has been received via telephone call from a physician indicating that the patient received the first dose of GARDASIL on 20-OCT-2006 (Lot number unavailable to the physician). The patient received the second dose of GARDASIL on 20-DEC-2006 (Lot number unavailable to the physician) and the third dose of GARDASIL on 01-MAY-2007 (Lot number unavailable to the physician). The physician stated that the lot number records for the GARDASIL vaccinations were accidentally discarded. The physician stated that she had changed her Physician Practice and had not seen the patient in over one year. The physician confirmed that the patient was hospitalized sometime at the end of February 2007 and was discharged from the hospital on 07-MAR-2007. The physician confirmed that the patient was diagnosed with Gastroparesis. The health care professional contacted during telephone follow-up could not supply the following information: lot number (if applicable). Additional information has been requested. 9/1/09 MR received for DOS 2/28-/06/2007 with D/C DX: Gastropar

Other Meds: None

Lab Data: Unknown Labs and Diagnostics: Gastric Emptying study (+) for decreased bowel transit time. Hepatobiliary scan WNL. CT abdomen (+) for ovarian cyst, fluid in abd, and lower throacic vertebrae end plate irregularity. Abd US unremarkable.

History: None PMH: wrist surgery, shingles, pertussis rxn./

Prex Illness:

Prex Vax Illns:

Vaers Id: **354363-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2009	12-Aug-2009	0	17-Aug-2009	26-Aug-2009	CA		26-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	UF480BA	5	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2909AA	0	Left arm	Intramuscular	
MMR	MERCK & CO. INC.	1673X	1	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0279X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334CA	0	Right arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB737AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Ear discomfort, Headache, Heart rate increased, Respiratory rate increased, Vital capacity

Symptom Text: Started feeling dizzy, ears felt plugged, then started with headache, + started having breathing difficulty. EPIPEN given 0.3 ml @ 1:44 PM vitals P-100, B/D 120/60 R 22,

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354364-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Aug-2009	04-Aug-2009	1	17-Aug-2009	26-Aug-2009	CA		26-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF452BA		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0279X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Oedema peripheral, Skin warm

Symptom Text: Mom and daughter back today. Patient (R) arm red, swollen, hot, hard to touch. Mother states patient has allergies to NEOSPORIN down latex? 100m x 120m - reaction site Started 8/4/09 around 1000 mm mother gave TYLENOL 500 mg this AM referred to PCP or ER for follow - up.

Other Meds:

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **354379-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Aug-2009	06-Aug-2009	1	17-Aug-2009	27-Aug-2009	NH		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC526040AB		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0087Y	2	Left leg	Intramuscular	
	VARCEL	MERCK & CO. INC.	0334Y	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea, Oropharyngeal pain, Upper respiratory tract congestion

Symptom Text: Pt vaccinated 8-5-09. Onset 8-6-09 with headaches sore throat, nausea and congestion. On 8-11-09 seen at local walk-n clinic now complaining of dizzyness, and other symptoms described. No fever, Negative Step. Encouraged ACETAMINOPHEN and fluids.

Other Meds: None

Lab Data: Negative Strep

History: Dymenorrhea

Prex Illness: None

Prex Vax Illns: Headaches~HPV (no brand name)~2~14.00~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354385-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Aug-2009	10-Aug-2009	0	17-Aug-2009	27-Aug-2009	OH		27-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1674X	0	Right arm	Intramuscular	MNQ
							TDAP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Skin warm, Vision blurred

Symptom Text: 12 minutes after injection patient got warm, vision blurred, then nausea. Pt was laid down with cool wash cloth + given juice. Pt was slowly sat up at different levels until sitting straight over a 10 minute time frame. Pt warm 15 more minutes then left with self. since she had no more side effects.

Other Meds: Pt on LOESTRIN

Lab Data:

History: PCOS

Prex Illness: NKA

Prex Vax Illns:

Vaers Id: **354407-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Aug-2009	17-Aug-2009	0	17-Aug-2009	26-Aug-2009	VA		26-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	VARCEL

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Cold sweat, Feeling cold, Lethargy, Loss of consciousness

Symptom Text: AFTER RECEIVING 1ST GARDASIL VACCINE, PT AND MOTHER RETURNED TO CHECK-OUT WINDOW AND STATED THE PT "COULDN'T SEE." PT BROUGHT BACK TO TRIAGE ROOM WHERE SHE WAS VERY COOL, CLAMMY, AND LETHARGIC. SHE WAS TAKEN BACK TO EXAM ROOM AND WAS BEING HELPED UP ON TABLE WHEN SHE PASSED OUT. PT DID NOT FALL SINCE NURSE AND MOTHER WERE ASSISTING HER. PHYSICIAN MADE AWARE AND WENT TO EXAMINE PT. SHE SOON AWOKE WHILE HE WAS PERFORMING ASSESSMENT. PT RESTED FOR 15 MINS AND WAS ABLE TO WALK AROUND IN HALLWAY BEFORE LEAVING BUILDING.

Other Meds: NA

Lab Data: GLUCOSE 89

History: OCCASSIONAL MIGRAINES

Prex Illness: NA

Prex Vax Illns:

Vaers Id: 354421-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Aug-2009	10-Aug-2009	3	17-Aug-2009	27-Aug-2009	MT		27-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Lymphadenopathy, Nausea, Pain, Vomiting

Symptom Text: Vaccine on 8-7-09. 8-10-09 elevated temp 104, nausea, vomiting (x1) severe nausea sore. No diarrhea. No local reaction. Swollen glands. BRAT diet, elevated fluids, Prilosec OTC OD.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354422-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Aug-2009	17-Aug-2009	0	17-Aug-2009	27-Aug-2009	OH		27-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1715X	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0558X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, Postictal state

Symptom Text: 20 m after given GARDASIL, had 20- second ser. tonic - clonic sz with mild postictal phase > 10m after.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354423-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Aug-2009	14-Aug-2009	1	17-Aug-2009	27-Aug-2009	TX		27-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0728Y	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0576X		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ocular hyperaemia, Oedema peripheral

Symptom Text: Pts arm got swollen up and pt had a red spot in the bottom of both eyes.

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354425-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Aug-2009	11-Aug-2009	0	17-Aug-2009	27-Aug-2009	NC		27-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0312Y	1	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	B041BA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	B296BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Unresponsive to stimuli

Symptom Text: 2-3 min after immunization of HPV given, patient swayed back + then fell to Rt side. Mother + myself called her name with no response for @ 3 seconds. Patient came to held in office for an additional 20 minutes.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **354429-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	11-Aug-2009	11-Aug-2009	0	17-Aug-2009	27-Aug-2009	NC		16-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Immediate post-injection reaction, Injection site pain, Musculoskeletal stiffness, Posturing, Unresponsive to stimuli

Symptom Text: HPV injection given IM in R deltoid. Immediately after pt c/o pain at site. 2 minutes after injection pt was sitting in chair. Unresponsive to verbal stimulus. Head tilted to left. Both hands began to jerk inward simultaneously and L leg was stretched forward. Episode lasted approximately 5 seconds and pt responded to verbal/physical stimuli. Pt's memory of event. VSS.

Other Meds: ADVAIR; ALBUTEROL; PREVACID; Allergy injections; VERAMYST; ZYRTEC

Lab Data: Pt sent for MRI of brain; EEG and CMP (results pending)

History: Trees; Grass; Mite; Cat; Molds (receives allergy shots)

Prex Illness: None

Prex Vax Illns:

Vaers Id: **354430-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Aug-2009	12-Aug-2009	0	17-Aug-2009	27-Aug-2009	MD		27-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	C3060AA	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Memory impairment, Pallor, Syncope

Symptom Text: Immediately became pale and fainted - revived in at 15 seconds but couldn't remember what happened.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354433-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	07-Aug-2009	07-Aug-2009	0	17-Aug-2009	27-Aug-2009	FL		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0313Y	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Headache, Inappropriate schedule of drug administration, Nausea, Tremor, Vomiting, Wrong technique in drug usage process

Symptom Text: 2:30pm Nausea / emesis shaking headache BP 110/78 sent to ER Home and feeling was hot seen at ER. was taking to long.

Other Meds:

Lab Data:

History: NKDA - Healthy

Prex Illness: None

Prex Vax Illns:

Vaers Id: 354460-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Mar-2009	07-Apr-2009	19	18-Aug-2009	19-Aug-2009	FR	WAES0908USA01971	19-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthma exercise induced

Symptom Text: Information has been received from a health Authority (#DK-DKMA-20091655), concerning a 12 year old female who on 19-Mar-2009 was vaccinated intramuscularly with the first dose of GARDASIL (batch number and site of administration not reported). On 07-Apr-2009 the patient experienced exercise induced asthma. It was reported that the patient had not recovered. The patient had no relevant medical history and received no concomitant medications or vaccine. Asthma exercise induced was considered to be disabling. Other business partner numbers included: E2009-07864. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 354461-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	10-Apr-2008	10-Apr-2008	0	18-Aug-2009	19-Aug-2009	FR	WAES0908USA00503	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0251U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arrhythmia, Cardiac neurosis, Chest discomfort, Dizziness, Feeling hot, Heart rate increased, Hyperhidrosis, Immediate post-injection reaction, Panic attack, Presyncope, Tachycardia

Symptom Text: Information has been received from a general practitioner on 13-JUL-2009 concerning a 22-year-old female patient who was vaccinated with a second does of GARDASIL (LOT#, injection site and route not reported) in year 2008 (three-quarter year prior to reporting date). Immediately, post vaccination, the patient experienced presyncope. She had recovered at that time. The event reoccurred in the further course of a three-quarter year. Several investigations (unspecified) were carried out and showed no pathological findings. Outcome was not reported. Follow-up information received on 11-AUG-2009. This case was upgraded due to hospitalization of the patient. Several medical letters, the hospital report and the reporting from where sent by the reporter. It was reported that the 21-year-old female patient with medical history of thoracic syndrome with intercostal neuralgia as neurodermatitis and alleged valvular heart defect in childhood was vaccinated with a third dose of GARDASIL (LOT# 0251U, Batch# NF65480) IM into the upper arm on 10-APR-2008. Concomitant medication included a hormonal contraceptive for system use. 1.5 hours post vaccination she suddenly developed dizziness, sensation of heat, retrosternal pressure, a rapid pulse, presyncopial condition, panic attack, cardiac arrhythmia and tachycardia. She also complained about sweating attack and was hospitalized on the same day. After she laid down symptoms improved. Over the course of time the patient showed similar symptoms twice. ECG (long term and at rest) showed no pathological findings. Transthoracal echocardiography was carried out on 11-APR-2008 and showed no indication of relevant haemodynamic valvular heart defect. A haemodynamic relevant cardiac arrhythmia was also ruled out. On 11-APR-2008 the patient was discharged in a good general condition. Because of relapsing thoracal discomfort the patient presented at a cardiologist on 18-JUL-2008. A moderate prolapse of the anterior mitral valve cusp with minimal, not haemodynamic relevant mitral valve insuffi

Other Meds: Hormonal contraceptives (unspecified)

Lab Data: transthoracic echocardiography, 11Apr08, no indication of relevant haemodynamic valvular heart defect; transthoracic echocardiography, 11Apr08, hemodynamic relevant cardiac arrhythmia ruled out; echocardiography, 18Jul08, A moderate prolaps

History: Intercostal neuralgia; Neurodermatitis; Heart valve incompetence; Thoracic outlet syndrome

Prex Illness:

Prex Vax Illns:

Vaers Id: **354462-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Feb-2009	29-Mar-2009	36	18-Aug-2009	19-Aug-2009	FR	WAES0908USA01518	19-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received on 06-AUG-2009 from the Health Authority (reference # ES-AGEMED-615706233) concerning a 14 year old female with no other relevant history reported who on 21-FEB-2009 was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL (lot# , site of administration not reported). On 29-MAR-2009 the patient experienced a convulsion that lasted 5 minutes, the patient recovered. Case is closed. Case reported as serious by the HA with other medically important condition as criteria. Other business partner numbers included: E2009-07846. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 354463-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Jul-2009	27-Jul-2009	0	18-Aug-2009	19-Aug-2009	FL	WAES0908USA01728	19-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall, Head injury, Posturing, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a physician concerning a "17-18 years old" female who "about two weeks ago" (approximately 28-JUL-2009) was vaccinated intramuscularly with the first dose of GARDASIL (LOT# not reported). There was no concomitant medication. After vaccination, the patient was taken to the waiting room where she fell backwards and hit her head. She was helped up and fainted for a second time. The physician stated that she was showing "posturing seizure-like activity" and that she was "obviously seizing". The office called 911 and an ambulance came to bring the patient to the emergency room. The physician followed-up with the patient in the office the next day, and he believed that the patient had recovered. No further information was available at the time of this report. Follow-up information has been received via a telephone call from the physician. It was reported that the 18 years old patient with no pertinent medical history and no known drug allergies on 27-JUL-2009 was vaccinated intramuscularly with the first dose of GARDASIL (LOT# 661953/1130X). There was no concomitant medication. On 27-JUL-2009, five minutes after vaccination, the patient experienced seizure activity which included tonic-clonic movements. The patient was taken to the emergency room. A CT scan of the head was performed on that day, and the result was negative. The patient was not admitted. Two days later, the patient was seen in the office and she had fully recovered. She was not referred to neurology. Additional information is not expected.

Other Meds: None

Lab Data: head computed axial, 07/27/09, negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 354464-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Aug-2009	05-Aug-2009	0	18-Aug-2009	19-Aug-2009	CA	WAES0908USA01924	19-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Grand mal convulsion, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 17 year old female with childhood seizures from age 5-11 years old and had been seizure free since 11 years old and with no drug reactions/allergies. On 05-AUG-2009 the patient was vaccinated IM with the first 0.5ml dose of GARDASIL. The patient had been on DEPAKOTE (last dose was at age 13). On 05-AUG-2009 three hours after she received GARDASIL the patient had a grand mal seizure with loss of consciousness. The patient was seen in the emergency room at the hospital. There was no family history of seizure noted. The lab diagnostics studies performed: Genetic blood tests, "CBC", "CMP" urine analysis, "EKG" and all were negative. The patient was scheduled for a 48 hours Electroencephalography (EEG) next week. The physician requested to have WAES form faxed to him and he would provide all needed information. At the time of report the patient's status was recovering. Upon internal review, grand mal seizure was determined to be an other medical event. Attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: electrocardiogram, negative; diagnostic laboratory, "CMP" urine analysis; hematology, genetic blood tests negative; complete blood cell, negative

History: Convulsion in childhood

Prex Illness:

Prex Vax Illns:

Vaers Id: **354465-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2009	01-Jul-2009	0	18-Aug-2009	19-Aug-2009	KS	WAES0908USA01957	19-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, Immediate post-injection reaction

Symptom Text: Information has been received from a physician concerning a 16 year old female who in approximately July 2009 (about 1 month ago), was vaccinated with the first dose of GARDASIL (lot#, route and site of administration not reported). The patient experienced a tonic-clonic seizure almost immediately after vaccination. Her symptoms resolved quickly in about 10 to 15 minutes. Unspecified medical attention was sought. No lab diagnostics studies were performed. On an unspecified date, the patient recovered. Upon internal review, tonic-clonic seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **354466-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Jul-2009	06-Jul-2009	0	18-Aug-2009	19-Aug-2009	FR	WAES0908USA01972	19-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Pruritus, Urticaria

Symptom Text: Information has been received from a health authority (reference number PEI2009016731). It was reported by a pediatrician that a 13-year-old female patient was vaccinated with the second dose of GARDASIL (lot no., injection site not reported) intramuscularly on 06-JUL-2009. On the same day the patient developed generalized urticaria with pruritus and hives. She was treated with SOLU-DECORTIN and FENISTIL IV and had recovered after "half a day". Dose one of GARDASIL given on an unknown date was well tolerated. Change in laboratory parameters in relation to the adverse event. Upon internal review events were considered medically significant. Other business partner numbers include: E2009-07887. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **354472-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-May-2009	25-May-2009	14	18-Aug-2009	24-Aug-2009	NC		26-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB296AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1326X		Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2912AA		Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Autonomic nervous system imbalance, Blood product transfusion, Cough, Decreased appetite, Diarrhoea, Faecaloma, Gait disturbance, Guillain-Barre syndrome, Headache, Hypoaesthesia, Hyporeflexia, Muscular weakness, Pain, Pain in extremity, Rhinitis allergic, Vomiting

Symptom Text: Severe headaches, belly pain, bilateral feet-legs tingling numbness, legs aching while walking, weakness in upper and lower extremities - happened 2 wks after vaccinations - patient was hospitalized. 8/24/09 Hospital records received - 2 admissions. DOS 6/10/09 to 6/14/09 Assessment: Guillain-Bare Syndrome. Allergic rhinitis. Transfered from another hospital ED. Presented with leg pain and weakness, headache, cough, and intermittant abdominal pain for 2 weeks. Vomiting. Difficulty walking, legs buckled. Decreased patellar DTRs bilaterally, unsteady gait. Anterior thigh pain, 'stinging' sensations in feet. IVIG administered. DOS 6/16/09 to 6/23/09. Assessment: Guillain-Bare Syndrome. Allergic rhinitis. Patient returned with recurrent headache and abdominal pain. Dysautonomia associated with GBS. Decreased appetite. Fecal impaction. Large amount of loose stool with resolution of abdominal pain. ICD-9 Codes: 357.0 Acute infective polyneuritis, V17.49 Family history of cardiovascular diseases, 455.6 Unspecified hemorrhoids without complication, 789.00 Abdominal pain unspecified site, 477.9 Allergic rhinitis cause unspecified, 518.89 Other diseases of lung, 792.0 Nonspecific abnormal findings in cerebrospinal fluid, 790.99 Nonspecific findings on examination of blood, 787.91 Diarrhea, 346.20 Varients of migraine.

Other Meds:

Lab Data: LABS and DIAGNOSTICS 6/10/09 to 6/14/09: Lumbar Puncture - elevated protein 207 mg/dL. MRI - Abnormal signal in cauda equina. LABS and DIAGNOSTICS 6/16/09 to 6/23/09.: X-Ray Abdominal Obstruction Series - No Significant Findings. Chest X-r

History: Seasonal allergies

Prex Illness: Healthy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354475-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Aug-2009	08-Aug-2009	0	18-Aug-2009	27-Aug-2009	MO		27-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB28713	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	C129121AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3098AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Pyrexia, Vomiting

Symptom Text: Fever - Nausea x 2 days - vomiting - headache - oral rehydration and MOTRIN for treatment.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354482-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Aug-2009	11-Aug-2009	0	18-Aug-2009	27-Aug-2009	OR		21-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	1604X	1	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2918AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0650X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonia, Loss of consciousness

Symptom Text: About 5 min after receiving the below 3 immunizations, pt. slumped fwd from sitting position on exam table, losing consciousness. M.D. caught upper body so didn't fall off table & with mother's help moved to supine position when awoke about 30 sec later (out about 30 sec). No post ictal state. NL neuro.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 354485-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jul-2009	29-Jul-2009	0	18-Aug-2009	27-Aug-2009	VA		03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Breath sounds abnormal, Dysphagia, Dyspnoea, Foaming at mouth, Scar, Throat tightness, Vaccination complication

Symptom Text: 7/29/09 - Client called Health Department at approximately 3:40 with complaints of severe abdominal pain and "white foam coming from her mouth, after receiving GARDASIL vaccine. Client spoke with Administrative Assistant, who advised to call 911 and client was then transferred to the "Nurse of the Day, " for further evaluation. Client had hang up requiring Nurse to return call to client. No answer - Message was left for client to seek medical attention by calling 911 or going to ER. Documented time of Service (vaccine administration) at the Health Department was 12:30. 7/31/09 - Follow-up: Telephone call to client, client not available, spoke to family member. Family member states all signs and symptoms have resolved and that the Hospital diagnosis was a reaction to GARDASIL. Asked family member to provide copy of discharge instructions and advised that VAERS Report would be completed by this PHN. Family member verbalizes understanding and states that she will provide the requested documentation. 7/31/09 - Receipt of documentation: Family member presents to clinic with documentation of client's ER visit. Documentation received by Administrative Assistant. 8/04/09 - Completion of VAERS Report. 9/2/09 ER records received DOS 7/29/09. Assessment: Vaccine side effect. Abdominal pain. Patient developed intermittent abdominal cramping and difficulty swallowing. Shortness of breath. Diminshed breath sounds bilaterally. Abdomen is tender. Scar on chest. On day one of menstrual cycle. Throat initially felt tight but not now. Symptoms spontaneously resolved.

Other Meds: None reported

Lab Data: 9/2/09 ER records received DOS 7/29/09. LABS and DIAGNOSTICS: Urine pregnancy test (-).

History: NKDA; Allergy to crabs and mites; no other conditions reported. 9/2/09 ER records received DOS 7/29/09. Shellfish, environmental allergies. VSD repair as infant. menstrual cramps.

Prex Illness: None reported

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354487-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	31-Jul-2009	01-Aug-2009	1	18-Aug-2009	27-Aug-2009	WI		28-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929N		Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0206Y		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Decreased appetite, Ocular hyperaemia, Pyrexia

Symptom Text: About 12 hours after HPV & HEP A she had red glassy eyes, fever to 102 for 2 days, weakness, (generalized), arms weak & thighs, decreased appetite.

Other Meds: None

Lab Data:

History:

Prex Illness: UTI

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354497-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-Jul-2009	30-Jul-2009	1	18-Aug-2009	28-Aug-2009	WA		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2919AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0181U	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Eye pain, Headache, Injection site erythema, Injection site swelling, Injection site warmth, Myalgia

Symptom Text: 5:00 am following day awoke with bad headache. 8:00 am felt faint, sore muscles in arms and legs, (ADVIL) hurt to open eyes. Shot site slightly red. 10:30 am felt somewhat better, shot site swollen to (ice and heat to site) 3 inches, red and hot to touch. (We believe this was meningitis site, GARDASIL on other arm.)

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354499-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Aug-2009	10-Aug-2009	0	18-Aug-2009	27-Aug-2009	WI		28-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2912AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0575X	2	Right arm	Intramuscular	
	HEP	MERCK & CO. INC.	AHBVB531AA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysphagia, Fatigue, Nausea, Oropharyngeal pain, Pain, Pharyngeal oedema, Pyrexia

Symptom Text: 08/10/09 - @ approximately 3:15 pm patient had vaccinations by 5:00 pm developed fever, aches, nausea, tired. At 6:15 throat felt sore. 8/11/09 - at 6:15 AM throat felt swollen (internally.), fever (no thermometer). 08/12/09 - went to Dr. - Test influenza, no throat culture - Temp 99., patient - still felt ache and couldn't swallow Ibuprofen.

Other Meds: 100mg Sertraline daily

Lab Data: Rapid influenza, Neg

History: Depression

Prex Illness: Healthy

Prex Vax Illns: Fever~Vaccine not specified (no brand name)~UN~2~Patient|Fever~Vaccine not specified (no brand name)~UN~2~Sibling

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354501-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	04-Jun-2007	03-Aug-2009	791	18-Aug-2009	27-Aug-2009	TX		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0930U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Received GARDASIL 6/4/2007, 7/31/2007, 12/28/2007 - Normal PAP 6/13/2006, 6/14/2007, 3/26/2008 - ASCUS HPV + 8/3/2009.

Other Meds:

Lab Data: Normal PAP 6/13/2006, 6/14/2007, 3/26/2008; ASCUS HPV +, 8/13/2009

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354502-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Aug-2009	15-Aug-2009	0	18-Aug-2009	27-Aug-2009	TX		28-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	08834	1	Left arm	Unknown	
MNQ	SANOFI PASTEUR	U2909AA	0	Left arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B038CA	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	03124	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site swelling

Symptom Text: Itching swelling to vaccine site. ABX given from ER seen at PCP site.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 354520-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Mar-2008	15-Apr-2008	42	18-Aug-2009	24-Aug-2009	NY		15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1487U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Adverse reaction, Back pain, Biopsy lymph gland, Chemotherapy, Computerised tomogram abnormal, Condition aggravated, Ear pain, Hodgkins disease nodular sclerosis stage II supradiaphragmatic, Hypertension, Idiopathic urticaria, Lymphadenitis, Lymphadenopathy, Mass, Neck pain, Obesity, Pain, Polydipsia, Radiotherapy, Rash, Skin burning sensation, Urticaria

Symptom Text: My daughter had been suffering from extreme full body Uticaria for three years and had been treated with benadryl, allergy medications, hydrocortisone creams and occasionally would be put on prednisone med pacs to control the uticaria. Two or Three weeks after her second vaccine of gardisil she noticed a lump on her neck. I took her to her pediatrician and was prescibed an antibiotic for possible glndular infection. After the course of the antibiotics were finished she came to me about 20 days later and said the lump never went away and now it was bigger. I immediately went back to my pediatricians office the next day. He sent her for an iimmediate cat scan. The cat scan results were enlarged lymph glands in her head neck and chest.We rushed her to the hospital rigth from his office where she was admitted. A biopsy was performed and she was diganosed with lymphoma cancer stage two.(Hodgkins) I am sure that this was caused by the gardisil vaccine. 8/25/09-record received for DOS 5/12/06-for allergy specialist visit for C/O difficulty controlling hives present since 9/05. Impression: idopathic urticaria. 8/24/09 PCP and oncology medical records received DOS 4/15/08 to 5/15/09. Assessment: Hodgkin Lymphoma Nodular Sclerosing Type, Stage IIAd. Patient presents with painful burning rash on extremities. Urticaria, obesity, polydipsia. Hypertension. Ear pain. Cervical lymphadenitis. Chemotherapy and radiation. Pain neck and back - resolving radiation reactions.

Other Meds:

Lab Data: too many to list. would have to get medical records. 8/24/09 PCP and oncology medical records received DOS 4/15/08 to 5/15/09. LABS and DIAGNOSTICS: Cervical Lymph Node Biopsy - Abnormal, Hodgkin Lymphoma. CT Neck - Abnormal, diffuse cervic

History: Same as #18. 8/24/09 PCP and oncology medical records received DOS 4/15/08 to 5/15/09. Persistant urticaria, penicillin allergy, allergy cat dander. \ksk

Prex Illness: consistant extreme full body Uticaria

Prex Vax Illns:

Vaers Id: **354523-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	07-Jul-2008	16-Aug-2008	40	19-Aug-2009	24-Aug-2009	KY		09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Chemotherapy, Glossectomy, Gynaecological examination, Lip and/or oral cavity cancer, Metastatic neoplasm, Neck mass, Parotidectomy, Radical neck dissection, Radiotherapy, Recurrent cancer, Squamous cell carcinoma, Surgery, Tongue ulceration

Symptom Text: I received the 1st round of Gardasil July 7, 2008. Towards the end of August 2009 a lesion formed on my tongue. I have been diagnosed with Oral Cancer. I have had 2 surgeries and will be completing Radiation and Chemo. 8/20/09 GYN medical records received. Annual GYN Exam. 8/20/09 GYN medical records received. Annual GYN Exam. 9/8/09 Head & Neck Clinic consultation records DOS 12/19/08 to 8/14/09 Assessment: Recurrent T2N2cM0 Squamous Cell Carcinoma of the left lateral oral tongue with extracapsular spread. Patient presented with a sore area on her tongue which was persistant and progressed. Intraoral partial glossectomy, modified neck dissection. T2N1M0 squamous cell carcinoma. Left and right sided neck mass. Left parotidectomy and bilateral neck dissections.

Other Meds:

Lab Data: Dr Visits, Biopsy, CT/PET Scans. 8/20/09 GYN medical records received. Annual PAP Smear. 9/8/09 Head & Neck Clinic consultation records DOS 12/19/08 to 8/14/09. LABS and DIAGNOSTICS: Biopsy Tongue (+) - Moderately differentiated squamous ce

History: none. 9/8/09 Head & Neck Clinic consultation records DOS 12/19/08 to 8/14/09 Tobacco use, smoked for three years - quit 08/08. Alcohol use.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354524-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Aug-2009	Unknown		18-Aug-2009	27-Aug-2009	TN		28-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB311A	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2813AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2997AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: 12cm area of erythema at site of MENACTRA injection.

Other Meds:

Lab Data:

History: Seizure Disorder

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354570-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	05-May-2008	05-May-2008	0	19-Aug-2009	28-Aug-2009	WI		28-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0093X		Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1740U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pyrexia, Vomiting

Symptom Text: Nausea, vomiting, low grade fever x 2-3 days reported by mother (no office visit). Gave pain reliever, sx resolved.

Other Meds: None

Lab Data: None

History: None Known

Prex Illness: None

Prex Vax Illns: Same as above~HPV (Gardasil)~1~11~Patient

Vaers Id: 354581-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	13-Aug-2007	01-Nov-2007	80	19-Aug-2009	20-Aug-2009	--	WAES0908USA02226	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse concerning a 20 year old female who on 13-AUG-2007 was vaccinated intramuscularly on her left deltoid with the second dose of GARDASIL (Lot # 658222/0927U). Concomitant therapy included YASMIN. On 01-NOV-2007 two months after her second vaccination the patient experienced a seizure. The patient sought medical attention and went to an unspecified emergency room. The patient was prescribed TOPAMAX, DEPAKOTE, KEPPRA in the beginning of November 2007. The patient underwent two magnetic resonance imaging (MRI), two electroencephalography (EEG), two electrocardiogram (EKG) and a 24 hour EEG which were all negative. Unknown if the third dose of GARDASIL was given at the office as 05-AUG-2009. The patient recovered from seizure. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: YASMIN

Lab Data: Electroencephalography, 11/??/07, negative; Magnetic resonance, 11/??/07, negative; Electrocardiogram, 11/??/07, negative; Electroencephalography, 11/??/07, negative

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354582-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		19-Aug-2009	20-Aug-2009	FR	WAES0908USA02494	20-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dysphagia, Dysstasia, Gastrointestinal infection, Muscular weakness, Psychosomatic disease, Speech disorder

Symptom Text: Information has been received from a pharmacist concerning a 16 year old female with no other relevant history reported who on an unspecified date was vaccinated with a dose of GARDASIL (lot#, route and site of administration not reported). Some months post vaccination the patient experienced a gastrointestinal infection. She recovered. Subsequently the patient complained about weakness of arms and legs so that she nearly could not stand. On an unspecified date the patient was hospitalized for diagnostics. All investigations including lumbar puncture/cerebrospinal fluid (CSF) showed no pathologies. Diagnosis of suspicion of psychosomatic disease was established. An according treatment was started. Additional information was provided on 12-AUG-2009. Meanwhile the patient additionally had "difficulties in speaking and swallowing". At the time of reporting the patient had not recovered. The reporter dose rather not assume a causal relation to therapy with GARDASIL. Other business partner numbers included: E2009-07945. Additional information has been requested.

Other Meds: Unknown

Lab Data: spinal tap, no pathologies; cerebrospinal fluid culture, no pathologies

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **354630-1** **Related reports:** 354630-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	18-Aug-2009	18-Aug-2009	0	19-Aug-2009	28-Aug-2009	VA		31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Dyskinesia, Fall, Fatigue, Gaze palsy, Immediate post-injection reaction, Increased appetite, Moaning, No reaction on previous exposure to drug, Thirst

Symptom Text: Pt. had seizure like activity after the vaccination, this was her third dose, she had no adverse reactions with the previous two. She remembers feeling tired, hungry, thirsty immediately after the vaccination and she felt faint and fell to the floor, where she was found by a nurse to have jerking movements of her limbs and she was making moaning noise, her eyes were rolled up, she dis not recall this after, the jerking resolves in 1 minute ans she was fully awake and alert after that, she denied feeling tired, no headaches, vision changes, there was no bowel or bladder incontinence with it. Her vital signs were stable.

Other Meds: Tenex

Lab Data:

History: Tic disorder, OCD, Anxiety disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: **354630-2** **Related reports:** 354630-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	10-Aug-2009	18-Aug-2009	8	04-Sep-2009	08-Sep-2009	VA	WAES0908USA04838	08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, Postictal state, Syncope

Symptom Text: Information has been received from a physician concerning a 22 year old female teacher with tic disorder and anxiety who on 10-AUG-2009 at 4:00 pm was vaccinated intramuscularly in the left arm with the third dose of GARDASIL (lot# 662518/0087Y). There was no illness at the time of vaccination. Concomitant therapy included TENEX. On 18-AUG-2009 at 4:01 pm the patient had tonic clonic seizure (whatever was written there was crossed out) with syncope that lasted for a full minute. The patient had asymptomatic post ictal phase. The patient denied any discomfort symptom after her seizure. The outcome was unknown. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: TENEX

Lab Data: Unknown

History:

Prex Illness: Tic disorder, unspecified; Anxiety

Prex Vax Illns:

Vaers Id: **354631-1** **Related reports:** 354631-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Jul-2009	08-Aug-2009	18	19-Aug-2009	31-Aug-2009	MD		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: First injection of Garadsil was given to my daughter on July 21, 2009. A few weeks later her hair has begun to fall out severely. She has not had any change to her diet, no new medications, no new hair care products, in the past year. 9/4/09 Received vaccine & PCP medical records. Records reveal patient experienced general good health on 7/21/09. RTC on 8/18/09 w/hair loss.

Other Meds:

Lab Data: No tests have been performed yet. Visit to the pediatrician. No diagnosis given yet. Dermatologist appt. scheduled. 9/4/09 Medical records received w/LABS: WBC 12.0 (H), neutros 79%(H), lymphs 16%(L). TSH 3.450(L), T4 0.92(N). Lipas

History: none 9/4/09 Medical records received w/PMH: pertussis vax reaction 1995. PE tubesx 2, T&A, bronchitis, viral exanthem, OM, strep throat, cat bite, sinusitis, vaginitis, conjunctivitis, viral syndrome.

Prex Illness: none

Prex Vax Illns: crying uncontrollably~DTP (no brand name)~1~0~Patient

Vaers Id: **354631-2** **Related reports:** 354631-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Jul-2009	20-Aug-2009	30	03-Nov-2009	05-Nov-2009	MD		11-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Dizziness, Headache

Symptom Text: hairloss in August October headaches and dizziness

Other Meds: at 6 months cried uncontrollably after receiving DPT. doc said she had bad reaction and would not give her pertussis again.

Lab Data: visit to hospital resulted in being told that Gardasil could not have caused headaches or dizziness.

History: Pertussis

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354632-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Aug-2009	17-Aug-2009	0	19-Aug-2009	31-Aug-2009	TX		31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	3	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	AHAVB296AA	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Heart rate decreased, Nausea, Pallor, Presyncope

Symptom Text: Near Fainting Heart rate 52 pale poor cap refill, dizzy and nausea.

Other Meds:

Lab Data:

History: near faiting

Prex Illness: none

Prex Vax Illns:

Vaers Id: **354639-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Jun-2008	21-Jun-2008	18	19-Aug-2009	24-Aug-2009	CA		07-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Right arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Alopecia, Anaemia, Arthralgia, Butterfly rash, Dizziness, Dry skin, Dysmenorrhoea, Fatigue, Headache, Joint stiffness, Joint swelling, Leukopenia, Musculoskeletal stiffness, Pain in extremity, Polyarthritis, Rash, Rash generalised, Raynauds phenomenon, Vitiligo, Weight decreased

Symptom Text: Fatigue, dry skin, extreme fatigue, light headed, headache, increased menstrual cramps, Raynaud's disease, weight loss, hair loss, joint pain, facial rash, extreme joint pain, body rash. 9/16/09 Rheumatology records received DOS 4/28/09 to 9/9/09. Assesment: Systemic Lupus Erythematosus. Vitiligo. Patient presented with progressive fatigue and weight loss with impaired functional capacity. Joint pain, swelling, and stiffness at PIPs, MCPs and wristes. Malar rash and Raynauds of feet. Leukopenia, anemia. Inflammatory polyarthropathy.

Other Meds:

Lab Data: Systemic Lupus Erythematosus; Raynaud's. 9/16/09 Rheumatology records received DOS 4/28/09 to 9/9/09. LABS and DIAGNOSTICS: ANA (+), ds-DNA 38 IU/mL (+), SSA (+), SSB (+). ESR 30 (H). C3 74 (L). Complement C4C 5 mg/dL (L). 24 hr Urine - P

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **354644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	27-May-2009	Unknown		19-Aug-2009	28-Aug-2009	MN		28-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Patient Reported intermittent hives since first HPV vaccine.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354648-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Aug-2009	18-Aug-2009	0	19-Aug-2009	28-Aug-2009	MI		31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0670Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Pt observed following inj./ After 15 minutes pt appeared to be having seizure activity. Observed until able to leave with grandmother of her own accord.

Other Meds: None administered

Lab Data: None

History: Seizure disorder

Prex Illness: None

Prex Vax Illns:

Vaers Id: **354654-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Aug-2009	17-Aug-2009	0	19-Aug-2009	31-Aug-2009	CA		31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Pallor, Presyncope, Tremor

Symptom Text: stood up after injection and had probable vaso vagal response with full body tremor, lips turned pale, eyes rolled back, assisted to exam table tremors lasted a few seconds-less than a minute, vital signs taken WNL

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 354655-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Apr-2008	25-Jul-2009	460	19-Aug-2009	31-Aug-2009	LA		19-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Autoimmune thyroiditis, Convulsion, Gaze palsy, Hypotonia, Muscle twitching, Primary hypothyroidism, Syncope

Symptom Text: Had seizure 7/25/09. Had Mri & Ct scan & blood work. In August diagnosed with Hashimoto Thyroiditis & compensated hypothyroidism. 10/6/09 PCP medical records received DOS 7/30/08 to 8/27/08. Assessment: Syncope Follow up from ER. Seizure?. Eyes rolled back, twitching, then limp. Lasted 30 seconds. ```10/26/09 Received Endocrine medical records of 8/8/08-7/8/09. FINAL DX: Primary hypothyroidism secondary to acute immune thyroiditis(Hashimoto's thyroiditis).

Other Meds: Flonase

Lab Data: 10/6/09 PCP medical records received DOS 7/30/08 to 8/27/08. LABS and DIAGNOSTCS: CBC - RBC 3.84 Mill/uL (L) Hematocrit 34.3% (L) Abs Lymph 1409 cells/uL (L). TSH 3rd Gen 4.62 mIU/L (H). EEG - Normal.

History:

Prex Illness: None

Prex Vax Illns: Seizure; Hashimoto Thyroiditis; compensated hypothyroidism~HPV (Gardasil)~~12.00~Patient

Vaers Id: 354665-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Aug-2009	18-Aug-2009	0	19-Aug-2009	31-Aug-2009	IN		31-Aug-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2844AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2922AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0087Y	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB343BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Pallor, Tinnitus

Symptom Text: Administered four vaccines during immunization clinic visit. Within five minutes of injection, client became very pale, c/o of dizziness and lightheadedness, H/A and buzzing in ears. Client did not lose consciousness or fall. Client eased to floor, feet elevated, cool pack to back of neck and client given sucker. CLient alert during entire process. After 10-15 minutes client's status improved although she still had H/A and buzzing in ears, client changed to sitting position and then standing position over next 5 - 10 minutes and left office under the mother's care. Client's gait steady and she ambulated without assistance. Mother advised to have child eat once home and lay down. Mother called approximately one hour after leaving office to report, client dizzy intermittently, had severe H/A and buzzing in ears. Advised mom to notify MD of s/s.

Other Meds: None noted

Lab Data: None

History: latex

Prex Illness: none

Prex Vax Illns:

Vaers Id: **354671-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Feb-2008	29-Jan-2009	344	19-Aug-2009	24-Aug-2009	CA		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Anxiety, Chemotherapy, Headache, Hodgkins disease, Hodgkins disease nodular sclerosis stage unspecified, Lymphadenectomy, Lymphadenopathy, Migraine, Odynophagia, Oropharyngeal pain, Pallor, Photophobia, Rash, Sinusitis

Symptom Text: Pt received the Gardasil series of shots on July 20, 2007, Sept. 26,2007 and Feb. 20, 2008. In Jan. 2009, she told me (her mother) about a large lump on her neck. It had clearly been there for sometime based on it's size (4cm x 3cm) and consistency. The pediatrician thought this was a benign swollen lymph node, but subsequently, this was biopsied by a surgeon and Jennifer was diagnosed with Hodgkin's Lymphoma, nodular sclerosis type. While we understand that there is not live virus in the vaccine, we believe that there is an association between the generated immune reaction to the HPV recombinant protein and Hodgkin's Lymphoma. My daughter is now undergoing chemotherapy for her cancer. I sincerely hope the CDC will collect data on Gardasil and the onset of Hodgkin's lymphoma in young girls. 9/1/09 PCP medical records received DOS 7/15/08 to 1/19/09. Patient presents with anxiety, migraines, sinusitis. 9/1/09 PCP medical records received 2/17/09 to 7/17/09. Assessment: Lymphadenopathy. Patient presents with headache frontal, associated with nausea and vomiting. Three migraines last two weeks, throbbing, photophobia. Sore throat, unable to swallow. Cervical lymph nodes bilateral. Rash on abdomen. Swollen cervical lymph nodes 2 months left side. 9/21/09 Received ENT & Heme/Onc consults. FINAL DX: Hodgkins lymphoma, nodular sclerosing, stage IIA. Records reveal patient was pale & had firm left clavicular lymph node. Excisional biopsy done 7/23/09 revealed diagnosis. Tx w/chemotherapy & possibly radiation tx when chemo completed.

Other Meds:

Lab Data: CBC, CMP, CT, PET, supraclavicular lymph node biopsy. 9/1/09 PCP medical records received DOS 7/15/08 to 1/19/09. LABS and DIAGNOSTICS: Strep (-). 9/1/09 PCP medical records received 2/17/09 to 7/17/09. LABS and DIAGNOSTICS: Rapid Strep

History: 9/1/09 PCP medical records received DOS 7/15/08 to 1/19/09. Minocycline allergy. Fasting glucose elevated. 9/1/09 PCP medical records received 2/17/09 to 7/17/09. Allergy to nuts. 9/21/09 Received medical records w/PMH: acne under treatment. migraines. Allergy: tetracycline. Family hx: cancer & leukemia.

Prex Illness:

Prex Vax Illns:

Vaers Id: **354734-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	19-Sep-2007	19-Sep-2007	0	20-Aug-2009	21-Aug-2009	FR	WAES0712USA02273	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Labour complication, Premature labour

Symptom Text: Information has been received from a 28 year old female who on 19-SEP-2007 was vaccinated with her first dose of GARDASIL. There was no concomitant medication. She later discovered that she was pregnant at the time of the vaccination (gestation 4 weeks). LMP was reported to be 29-AUG-2007 and estimated delivery to be 29-MAY-2008. The patient has a history of two interrupted pregnancies with no reported complications or adverse events. At time of reporting patient had no AE. Follow up information has been received from consumer on 14-JUL-2009. The patient gave birth to twins on 04-MAY-2008 with acute cesarean section as one of the twins lay wrong when the water broke. The girl weighed 2525 g and was 46 cm tall and the boy weighted 2610 g and was 46 cm tall. They were admitted to neonatal department for observation as they were born 4 weeks early. No remarks on the test (unspecified) performed on the neonatal ward. The girl had two large birth marks (mark called "wild strawberry birth mark") on the side but the doctor told it was hurtless and common. It usually disappears before school age. There is nothing else to remark on so far. The pregnancy was told to be easy considered a twin pregnancy. The mother had decreased blood pressure and decreased iron value during pregnancy. The birth marks were still present at the time of reporting. A corrective version was created on 07-AUG-2009 to upgrade the case to serious and code adverse events. Labour complication, iron decreased and blood pressure decreased were considered to be other important medical events. Other business partner numbers included E2007-08874 and E2009-07903. Additional information is not expected. The case was closed.

Other Meds: Unknown

Lab Data: blood pressure measurement, Decreased during pregancy; laboratory test, Decreased iron level during pregancy

History:

Prex Illness: Pregnancy NOS (LMP = 29Aug07)

Prex Vax Illns:

Vaers Id: **354735-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Aug-2009	08-Aug-2009	0	20-Aug-2009	21-Aug-2009	FR	WAES0908USA02521	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope, Tonic clonic movements

Symptom Text: Initial information has been received on 12-AUG-2009 from the Health Authority (reference number ES-AGEMED-731434440) concerning a 12 year old female with no other relevant history who on 08-AUG-2009 was vaccinated with a dose of GARDASIL (lot#, route and site of administration not reported). On 08-AUG-2009 the patient experienced a syncope. In the Health Authority's report narrative field it was reported that the patient experienced a loss of consciousness with mild tonic clonic movements. In the report's adverse event box only adverse event code was syncope. On 08-AUG-2009 the patient recovered from syncope. Case reported as serious by the HA with other medically important condition as criteria. Case is closed. Other business partner numbers included: E2009-07981. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 354736-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Jul-2008	01-Oct-2008	92	20-Aug-2009	21-Aug-2009	FR	WAES0908USA02498	21-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Cardiac failure, Haemodialysis, Oral contraception, Pelvic venous thrombosis, Pericardial effusion, Pericardiotomy, Postoperative renal failure, Pulmonary embolism, Resuscitation, Thrombectomy

Symptom Text: Case received from health authority on 10-AUG-2009 under reference number PEI2009016714. Information has been received from an agency concerning a 22 year old female with a history of MIHFR gene mutation (MIHFR) who in July 2008, was vaccinated with the first dose of GARGASIL (lot#, route and site of administration not reported). In August 2008, she was vaccinated with the second dose of GARDASIL (lot#, route and site of administration not reported). On an unspecified date in September 2008 she was vaccinated with the third dose of GARDASIL (lot#, route and site of administration not reported). Concomitant therapy included hormonal contraceptive with VALETTE which was assumed by the reporter to be suspect drug, too. Toleration of the first two doses of GARDASIL were not reported. On 30-OCT-2008, about 2 weeks post vaccination, the patient experienced a fulminant pulmonary embolism due to subacute solitary left pelvic venous thrombosis. The patient had to be resuscitated several times. She was hospitalized. Pulmonary thrombectomy was carried out on 30-OCT-2008. Subsequently the patient developed right heart insufficiency and pericardial effusion. Pericardiotomy was carried out on 09-NOV-2008. Postoperative (exact onset not reported) the patient developed renal failure. Haemodialysis was carried out until 26-NOV-2008. Treatment with anticoagulants (not specified) was ongoing at the time of report to HA. The patient recovered completely and was discharged from hospital on 08-DEC-2008. Pulmonary embolism, pelvic venous thrombosis, resuscitation, thrombectomy, heart insufficiency, pericardial effusion, pericardiotomy, postoperative renal failure and haemodialysis were considered to be immediately life-threatening. Other business partner numbers included: E2009-07888. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Gene mutation

Prex Illness:

Prex Vax Illns:

Vaers Id: **354742-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	10-Feb-2009	14-Mar-2009	32	20-Aug-2009	31-Aug-2009	MN		31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune disorder, Hyperhidrosis, Muscle twitching, Muscular weakness, Rash pruritic, Urticaria chronic

Symptom Text: Had 2nd HPV vaccine 2/10/09; starting 3/24 begin with itchy rash over feet which spread to much of torso. By 4/09 developed muscle weakness & muscle twitches but no muscle pain. Also developed severe sweating. Had elevated ANA but also has celiac sprue & Type 1 DM. Has been seen by Rheum + Derm. No diagnoses made others than? chronic autoimmune urticaria.

Other Meds:

Lab Data: +ANA, 1:320

History: Insulin dependent + Diab Mellitus Type 1; Celiac Sprue; Pancreatitis; Increase chol.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354747-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Aug-2009	11-Aug-2009	0	20-Aug-2009	31-Aug-2009	NE		31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	C3028AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3028AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Left deltoid warm, red, swollen, painful, 7 cm X 8 cm.

Other Meds: QVAR; SINGULAIR; KOPENEX; ALVESCO

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354753-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Aug-2009	14-Aug-2009	2	20-Aug-2009	31-Aug-2009	NV		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2919AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0702X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0805Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Fatigue, Loss of consciousness

Symptom Text: Mom states pt felt tired yesterday, light headed dizziness, fell out & lost conciosness for 30 seconds today!

Other Meds: VYVANSE 20mg; ABILIFY 5mg

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354755-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Jul-2009	11-Jul-2009	0	20-Aug-2009	01-Sep-2009	--		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Gaze palsy, Headache, Musculoskeletal stiffness, Nausea, Pallor, Syncope

Symptom Text: Took my three daughters to their doctors for the GARDASIL shot. One daughter was fine, no reaction. The youngest daughter -11 years old- felt nauseous and went pale and had a mild headache. My oldest daughter -15 years old- is the one who had the severe reaction. I believe she had a seizure and not just fainted. She first complained of feeling nauseous then dizziness. Her eyeballs rolled in the back of her head and her whole body went stiff. I could barely lift her stiff legs on the table and lay her head down. After about a minute of calling her name, she finally woke up but was very pale and had a bad headache. The doctor just blew me off, but I will not let my daughters receive this shot again.

Other Meds:

Lab Data: None

History: My oldest daughter has seasonal allergies, ovarian cysts, but no other known medical conditions. My youngest daughter had a fever seizure as an infant we think because of the pertussis in the APT shot. She also had ADHD. My middle daughter -the one who had no reaction to the shot- also had ADD but no other medical conditions.

Prex Illness:

Prex Vax Illns:

Vaers Id: **354771-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-May-2007	15-Jun-2007	25	20-Aug-2009	31-Aug-2009	PA		06-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0388U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2135AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Adenotonsillectomy, Alopecia, Balance disorder, Dehydration, Dizziness, Ear congestion, Ear pain, Endolymphatic hydrops, Fatigue, Feeling cold, Heart rate increased, Hypoacusis, Joint injury, Migraine, Nausea, Pharyngitis, Postural orthostatic tachycardia syndrome, Snoring, Upper respiratory tract infection, Vestibular disorder, Vomiting

Symptom Text: Initially loss of hair. Then dizziness and nausea with vomiting and severe abdominal pain. After 20 months of multiple doctor visits, Nina was diagnoses with POTS, Postural Orthostatic Tachycardia Syndrome. She is required to take meds every 3 hours including a beta blocker. She has been on homebound study for her last 2 years of school. 9/29/09 PCP medical records and multiple consultations received DOS 7/18/05 to 10/2/08. Assessment: Vestibular hypofunction. Patient presents with otalgia, ears fell clogged. Injured ankle. Pharyngitis, URI. Hair falling out, dizziness. Feels cold. Orthostatic tachycardia. Snores. Progressive fatigue. Dehydration. Sudden increased heart rate at rest with nausea. Cardiologist - Normal cardiac exam. ENT Consult performed T&A. Peripheral vestibular lesion. Vomiting, stomach pain. Neuro consult - migraine varient. Feels off balance. Otology Consult - Transient decreased hearing (R). Visual vestibular hypersensitivity. Vestibular hydrops.

Other Meds:

Lab Data: Tilt table test and echocardiogram. 9/29/09 PCP medical records and multiple consultations received DOS 7/18/05 to 10/2/08. LABS and DIAGNOSTICS: Normal ECG and Echocardiogram. CT Scan (-). ENG hypoactive. Audiometic - Abnormal. Rotary cha

History: none. 9/29/09 PCP medical records and multiple consultations received DOS 7/18/05 to 10/2/08. Exercise-induced asthma. Allergic rhinitis. Allergy to household dust. 10/5/09 Vaccine records received: Hep A #1, SKB, given 10/1/08, lot# AHAVB246AA, LA. Flu shot, Conn, given 10/1/08, lot# U278414A.

Prex Illness: No

Prex Vax Illns:

Vaers Id: 354775-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Oct-2008	20-Oct-2008	12	20-Aug-2009	25-Aug-2009	TN		31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain lower, Acute sinusitis, Anaemia, Asthenia, Chest pain, Cough, Erythema, Fatigue, Headache, Herpes zoster, Hypophagia, Impaired self-care, Malaise, Mobility decreased, Muscle spasms, Muscular weakness, Oral candidiasis, Oropharyngeal pain, Otitis externa, Pain, Post herpetic neuralgia, Pyrexia, Rash, Rash papular, Upper respiratory tract infection, Urine output decreased, Vulvovaginal candidiasis

Symptom Text: 1st vaccination was on 07/15/08, she began having muscle cramps primarily in legs. 2nd vaccination was 10/8/08 and muscle cramps extended throughout the body and much more severe. She also began loosing her ability to use her arms, hands, and legs along with fever, headaches, severe body aches, anemia, and elevated liver enzymes.By mid Dec.08 she required total care including getting dressed, putting shoes on, bathing, washing hair, etc. 8/27/09 Hospital records received DOS 1/12/09. Assessment: Dermatomyositis Patient presents with recent history of increasing muscle weakness. ICD-9 Codes: 710.3 Juvenile Dermatomyositis. 8/27/09 Hospital records received DOS 1/12/09. Assessment: Dermatomyositis Patient presents with recent history of increasing muscle weakness. PMH: Allergies - Sulfa, egg yolks. Bladder cysts. ICD-9 Codes: 710.3 Juvenile Dermatomyositis. 8/28/09 Hospital records received 2/28/09 to 3/2/09. Discharge Diagnosis: Right lower quandrant pain, dermatomyositis. Patient presented with severe right lower quadrant pain. Recent upper respiratory infection. Rash consistant with dermatomyositis. Decreased PO intake, decreased urine output. 8/28/09 PCP medical records received DOS 7/15/08 to 8/21/09. Assessment: Oral and vaginal candidiasis. Dermatomyositis. Shingles with post herpetic neuralgia/itching. Patient c/o 'real weak spells, almost passed out". Chest hurts when coughing and inhaling. Malaise, fatigue. Swelling and red papular rash - periorbital area - since starting allergy injections. Fever. Vaginal yeast infection, thrush in mouth. Sore throat, abdominal pain. Acute sinusitis. Shingles. Otitis externa.

Other Meds: None at that time

Lab Data: Lab results found elevated muscle enzymes, sed rate, etc. Muscle Biopsy performed at Hospital in Jan 09 resulted in a confirmed dx of Juvenile Dermatomyositis. 8/27/09 Hospital records received DOS 1/12/09. LABS and DIAGNOSTICS: Muscle B

History: None at that time. 8/27/09 Hospital records received. DOS 1/12/09. Allergies - Sulfa, egg yolks. Bladder cysts. 8/27/09 Hospital records received DOS 1/12/09. Allergy to sulfa, egg yolks. Exercise induced asthma. Frequent urinary tract infection as infant with dilation of urethra and removal of vaginal lesion, PE tubes. 8/28/09 PCP medical records received DOS 7/15/08 to 8/21/09. M

Prex Illness: None

Prex Vax Illns: Muscle Cramps~HPV (Gardasil)~1~15~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354777-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	06-Aug-2009	08-Aug-2009	2	20-Aug-2009	31-Aug-2009	AZ		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2919AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF460AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0798Y	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Rash, Skin warm

Symptom Text: Red area to back of left arm the size of mom's fist with a rash going down the arm towards the elbow, warm to the touch.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **354784-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Aug-2009	07-Aug-2009	0	20-Aug-2009	31-Aug-2009	WA		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Inappropriate schedule of drug administration, Injection site pain, Muscle rigidity, Neck pain, No reaction on previous exposure to drug, Pain in extremity, Pallor, Presyncope, Syncope, Vomiting

Symptom Text: Patient had first Gardisil injection at her pediatric clinic without complications approximately 1 year ago. Gave 2nd Gardisil 0.5ml injection in L Deltoid on 8/7/09. Patient stated that it hurt then started to lean to the left side. Her body went rigid, hands clenched at chin level. She quickly sat up and opened eyes and became responsive. She was pale, diaphoretic, radial pulse of 58 bp 90/60. Placed her head between knees and did slow deep breathing. Patient stated she felt better. VS more stable...pulse 64, bp 96/62. Aproximately 10 minutes later, patient became pale, diaphoretic, dizzy c/o neck pain. Radial pulse 58, thready, bp 92/58. Staff called 911. Kept patients head down, slow breathing until EMT's arrived. Gave EMT's report of sx and vitals. Patient vomited x 2. Patient recovered. EMT's stated that she vasovagaled from the injection. She had not eaten dinner the night before or breakfast or had anything to drink since the night before which may have contributed to the fainting as well. Patient did not want to go to ER...father signed release, patient left with dad and boyfriend.

Other Meds:

Lab Data:

History: No Allergies, Migraine headaches, Smoker.

Prex Illness: Possible dehydration- patient told EMT's that she had not had anything to eat or drink since the day before her injection.

Prex Vax Illns:

Vaers Id: 354791-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-Jan-2008	27-Mar-2008	71	20-Aug-2009	25-Aug-2009	UT		06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Activities of daily living impaired, Aphasia, Blood lactic acid increased, Conversion disorder, Convulsion, Diplopia, Dysphemia, Dysstasia, Eructation, Fatigue, Fluid retention, Gait disturbance, Grip strength decreased, Hemiparesis, Hypoglycaemia, Malaise, Ovarian cyst, Panic attack, Paraesthesia, Pelvic pain, Pyrexia, Retching, Sensation of heaviness, Sensory disturbance, Sinus tachycardia, Speech disorder, Staring, Subcutaneous abscess, Supraventricular tachycardia, Syncope, Tachycardia, Thyroid neoplasm, Tremor, Vision blurred, Walking aid user, Wheelchair user

Symptom Text: She started having "seizures" or "staring episodes" and her eyes started getting blurry or double vision at times in June 2008. She was so sick she was admitted to the hospital that month. The only thing they found was SVT. Feb 2009 they found she has hypoglycemia. May 2009 She started having slow speech and started dragging her left leg. June 2009 Both legs started feeling "tingly" and heavy- she couldn't support herself all the time. She is in a wheelchair more that not, or uses a walker the rest of the time. She can't speak at all at times- it comes out like baby jibberish or child like speach. July 2009 she started retaining water?? We noticed she had cushy bags on her back that come and go. Also that month she started "gagging" like she was going to throw up, but nothing comes out- except maybe a burp. Everyday she feels sick. Her life has completely been ruined becuase she is too sick to do anything. We have taken her to several types of doctors, but they said they think it is a "conversion disorder" because they haven't found what is causing it all. I know better than that. It is a cop-out to label it as that just because they don't know what is wrong. All these symptoms started after she had the Gardasil Vaccinations. I know this has caused the problems! 9/17/09 ER / hospital records received 4/5/08 to 5/27/09. Many visits and complaints, extensive diagnostic testing. Assessment: Left side weakness, aphasia. Conversion disorder. Originally presents with pelvic pain and a history of cysts. Epigastric pain. Right ovarian cysts. Sinus tachycardia, syncopal episode. Thyroid nodule. Patient later presents with difficulty standing, imparied speech, stuttering, difficulty walking, dragging (L) foot, weak grip. Subsequent visits: tachycardia, abdominal pain, elevated lactate. Presented to emergency room with many episodes of shaking, blurred vision, and could not talk. Begin as a "lightness" or "tightening sensation" all over body. Fever. Panic attacks. Fatigued and tired.

Other Meds: 9/17/09 ER records received 4/5/08 to 5/27/09. NuvaRing.

Lab Data: 3/27/08 urinalysis w/o 6/21/08- CT. 6/22/08 Echo, transthoracic (2D), doppler, cardiography color flow velocity mapping. 6/23/08 MRI brain w/o contrast- ultrasound pelvic. 6/25/08 Ultrasound soft tissue head/neck/thyroid. 7/10/08 EEG.

History: 9/17/09 ER records received 4/5/08 to 5/27/09. Thyroid cyst. Ovarian Cyst. 10/05/09 Vaccine records received: HPV #2, Merck, given 10/15/08, lot# 1061U, RA; Adacel, Sanofi, given 10/15/08, lot# C2768BA, LA; Twinrix, given 10/15/08, no lot # provided.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Jul-2009	26-Jul-2009	5	20-Aug-2009	27-Aug-2009	ND		17-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1103X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Anorexia, Depressed level of consciousness, Fatigue, Heart rate increased, Loss of consciousness, Malaise, Postural orthostatic tachycardia syndrome

Symptom Text: ON July 21 had shot. On July 26 passed out 4 times at the fair. August 3 blacked out but she said didn't pass out all the way. Aug 10 not feeling well feels tired and stomach hurts when standing. Aug 11 took to doctor. Aug 12 passed out at the mall. Always very tired. Doesn't like to eat makes her sick. Was fine before this. 9/15/09 Received vaccine & PCP medical records. Records revealed patient experienced general good health on day of HPV #1.

Other Meds: none

Lab Data: She was told she has pots disease. Urin and blood work and EKG were good. Heart rate goes way up when sitting, to standing. It was the gardasil shot. Not sure if I marked the right one. Health Unit asked me to fill this out. My doctor

History: none 9/15/09 Received medical records w/PMH: Allergy: PCN.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354799-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	13-Aug-2009	Unknown		20-Aug-2009	31-Aug-2009	ND		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Rash pruritic, Skin exfoliation

Symptom Text: patient developed a hive appearance rash on 1 side of the face approx. 2 hrs. after receiving her 1st dose of gardasil. The following day rash deeper red with small bumps and itchy. Same rash developed on cheeks bilaterally by day 3, and continued times 5 days total. Benadry given times 4 doses for 48 hrs. after injection. day 5 patients skin on cheeks peeled as if sunburned.

Other Meds:

Lab Data:

History: Seafood-hives, sudafed-hyperactive, metal-rash.

Prex Illness:

Prex Vax Illns:

Vaers Id: **354800-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	11-Jun-2009	15-Jul-2009	34	20-Aug-2009	31-Aug-2009	OH		18-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Syncope

Symptom Text: FAINTING, DIZZYNESS HEADACHE , STARTED THESE FAINTING SPELLS AFTER THE 2ND SHOT THAT WAS IN 6/09 HAS FAINTED 6 TIMES. PUT ON BETA BLOCKER AND FLORINEF BY DOCTOR,BEEN TO TWO SPECIALIST FOR HEART, MAY WANT TO PUT IN PACE MAKER. WAS DIAGNOSED WITH NEUROCARDIOGENIC SYNCOPE. WE ARE VERY INTERESTED TO FIND ABOUT HOW TO BE DETOXED FROM THESE SHOTS 12/31/09 Medical records received for date 6/11/09. Pt had OV for vax. No other info provided. ``` MR received for date 7/22/09 and 8/12/09. Cardiac consult. DX: syncope. CC: 6 months ago started having syncopal episodes, recent weeks occurring more frequently. 8/12 tilt test WNL. Just prior to tilt test pt had witnessed syncopal episode w/ sinus arrest lasting 14-17 seconds. Pt returned to normal SR. tilt test aborted. ```MR received for date 8/17/09. Cardiac consult. DX: syncope and collapse, lightheadedness. Suggest pacemaker if episodes do not lessen in severity/frequency as prev. cardiac consult mentioned OV f/u cardiac consult. Pt decided to d/c all meds and attempt to detox body non-pharmacologically. CC: second opinion syncopal episodes. ```ICD Codes received: 780.2, 780.4.

Other Meds: BIRTH CONTROL - YAZ

Lab Data: EEG, EKG, CAT SCAN, HEART HALTER MONITOR, TILT TABLE TEST BLOOD WORK ```Diag/Labs: CT(-), EKG(-), EEG(-), holter monitor abnormal showing two pauses w/ poss vasovagel response, PVC, chemistry WNL, TSH WNL.

History: NONE ```PMH: migraine, cystitis.

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354801-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Aug-2009	19-Aug-2009	0	20-Aug-2009	31-Aug-2009	PA	2009PH01	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	MNQ TDAP VARCEL

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Heart rate increased, Immediate post-injection reaction, Syncope

Symptom Text: - approx 2 minutes post-vaccination: syncope, racing pulse, uncontrollable crying

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354802-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Aug-2009	14-Aug-2009	0	20-Aug-2009	31-Aug-2009	IL		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3016AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	03124	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF486AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Head injury, Immediate post-injection reaction, Syncope, Tremor

Symptom Text: Convulsive syncope 5min post vaccination. Mother reported child shaking, however, when nurse arrived child was awake and talking to mother. Mother states child hit her head on the floor, however, child never c/o pain in back of head. no swelling. Youth received Tdap, Menactra, and Gardasil.

Other Meds:

Lab Data:

History: Mother was surprised that child fainted with vaccinations because she has received allergy shots without problems. Child states had not eaten lunch.

Prex Illness: No

Prex Vax Illns:

Vaers Id: **354803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Aug-2009	17-Aug-2009	0	20-Aug-2009	31-Aug-2009	IL		01-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	UF486AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHA3311AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3016AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0570X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Client was given Tdap, Hep A, Menactra, and HPV. Syncope episode 10 min after vaccine adm. Child was assisted to the floor. Was responsive as soon as she was placed on the floor.

Other Meds:

Lab Data:

History:

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354806-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Aug-2009	12-Aug-2009	0	20-Aug-2009	31-Aug-2009	CA		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNC	WYETH PHARMACEUTICALS, INC	U2870AA		Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA		Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0121Y		Left arm	Subcutaneously	
	HEP	MERCK & CO. INC.	AHAVB244A0		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1127X		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: RAISED AREA LOA, APPROX.70MM X 70MM . NO OTHER SYMPTOMS.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **354808-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Aug-2009	19-Aug-2009	1	20-Aug-2009	31-Aug-2009	NE		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	500681P		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	0723Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0702X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain, Local reaction

Symptom Text: Large local reaction noted 2 days after vaccination in the L deltoid. Erythema, induration, pain at the site.

Other Meds: Desogen

Lab Data:

History: Depression

Prex Illness: No

Prex Vax Illns:

Vaers Id: **354810-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	01-Oct-2008		20-Aug-2009	01-Sep-2009	MA		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Mental disorder

Symptom Text: Shortly after receiving third dose of immunization, my daughter began to demostrate unusual psychological behavior. Atmosphere of self-destructiveness and potential Bi-Polar elements came about. As example, being in her senior year of highschool, she had scheduled several college visits and held a good deal of excitement about going to college for psychology or special education. Within a short time of receiving this vaccine, her performance in school tanked, she stopped visiting schools and began alienating her friends. In January she met a young man, got ingaged in 5 weeks, moved out 8 weeks later(still in school) and got married. I realize this could appear as a parent looking for an excuse for a child's ill behavior but the dramatic change and lack of having any accountability for actions, still, is at an unnerving level. Conversations with her still indicate no ability to understand impact of actions, behavior is completely reactionary. I also want to add that this is not only something which her parents noted, but her guidance counselor, her teachers and even the support counselor. On the last day of school the support counselor pulled me aside, knowing all that had changed overnight and said "There is something dramatically wrong with your daughter - her wiring has gone haywire, there's more to this than a child acting out". Would like to know if there are any other reports of psychological issues on other patience

Other Meds: Concerta

Lab Data:

History: ADD, Premature(28 week gestation)

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354811-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	17-Dec-2008	17-Dec-2008	0	20-Aug-2009	01-Sep-2009	NC		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Nausea, Paraesthesia

Symptom Text: Within seconds of receiving vaccine, I felt like I was going to pass out, nurse instructed me to lie down on table, she left and I passed out. This occurred probably within 30 seconds total after receiving vaccine. Ambulance arrived and while being transported to hospital, I felt tingling in hands and fingers and also felt incredibly nauseous. Also felt I was going to pass out again, but didn't. Arrived at hospital, still feeling nauseous and had many tests. Due to having a history of seizures and syncope, gynecologist and doctors at hospital dismissed symptoms as being anxious over having shot. I have given blood several times in the past few years and never passed out from that. It has been 8 months since vaccine and no other symptoms have occurred.

Other Meds: Sprintec 28-day

Lab Data:

History: Epilepsy - age 4-8, then diagnosed with syncope. Allergic to erythromycin.

Prex Illness:

Prex Vax Illns:

Vaers Id: **354814-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Aug-2009	15-Aug-2009	0	20-Aug-2009	01-Sep-2009	--		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Diarrhoea, Dizziness, Dysstasia, Pyrexia, Sleep disorder, Vaccine positive rechallenge

Symptom Text: I've had the same reaction to GARDASIL on both shots. The first shot I initially forgot about, on account of I was injected with three vaccines at once. The second shot I had today at 4:30 ish, and my symptoms began around 9:00. I began to have severe diarrhea until I began to have an absence of stools, and began to just have pure water in my bowel movements. It has continued for at least five hours, and shows no signs of stopping. I also have severe cramping in my abdomen, and seem to have a high fever. I cannot hold water or slight food in my stomach; it makes it worse to even drink. So now, I feel very faint and have a hard time sitting and standing. The first shot was much of the same. I was up all night with watery stools, and was told to report this adverse effect to the FDA.

Other Meds:

Lab Data: I have not had any relevant tests done to support my claims, because it was always late at night when my problems started, and our hospital isn't the best to be treated by.

History: I have no other relevant history. I don't have any drug uses or allergies. I haven't had any pre-existing conditions that could cause me to be so severely sick as I am.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354831-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Aug-2009	19-Aug-2009	0	20-Aug-2009	31-Aug-2009	AZ		31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3247AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0804Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2992AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0313X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Agitation, Dysphagia, Emotional disorder, Headache, Hypoaesthesia, Nausea, Pain in extremity

Symptom Text: c/o Headaches, Right arm numbness, R arm severe pain, nausea, agitated, hurts to swallow, emotional after HPV vaccine.

Other Meds: None

Lab Data:

History: Stress hyperglycemia

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354837-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Aug-2009	19-Aug-2009	0	20-Aug-2009	31-Aug-2009	AZ		31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0082Y	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Pleurisy

Symptom Text: Sudden onset left sided chest pain and pleurisy like symptoms approximately 4 hrs after vaccine.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **354843-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	17-Aug-2009	18-Aug-2009	1	20-Aug-2009	31-Aug-2009	VA		31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site rash, Injection site swelling, Injection site warmth

Symptom Text: Tues PM 8/18/09 left arm red swollen with heat and "rash" at injection site with itching at site of injection. Mom denies other symptoms and symptoms improved with BENADRYL.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Aug-2009	11-Aug-2009	0	20-Aug-2009	31-Aug-2009	TX		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2820AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y		Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3027AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site urticaria

Symptom Text: L Deltoid erythematous wheal

Other Meds:

Lab Data:

History:

Prex Illness: Keratosis

Prex Vax Illns:

Vaers Id: **354901-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	30-Jul-2009	30-Jul-2009	0	21-Aug-2009	24-Aug-2009	FR	WAES0908MEX00011	24-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Nausea, Syncope, Vomiting

Symptom Text: Information has been received from a health professional concerning a 9 year old female who on 30-JUL-2009 was vaccinated with GARDASIL first dose. There was no concomitant medication. On 30-JUL-2009 after the vaccine was administered, the patient experienced faint and convulsion (characterized by spastic contractions in hands and foot), after a few seconds, the patient recovered from faint and convulsion and referred that she felt dizziness, nausea and presented 2 episodes of vomiting, the reporter stated that patient did not require hospitalization. The patient under went observation for 45 minutes and recovered from dizziness, nausea and vomiting. The reporter stated that the patient hasn't neurological pathology history. The reporter stated that the patient's mother considered convulsion, dizziness, faint, nausea and vomiting were not related to therapy with GARDASIL, but were related to patient's "nervousness" before the vaccine administration. Upon internal review convulsion was considered as OME. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **354902-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		21-Aug-2009	24-Aug-2009	FR	WAES0908USA01577	24-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Convulsion, Fall

Symptom Text: Information has been received from a consumer via CSL as part of a business agreement and internet website concerning a 13 year old female patient with asthma who in approximately 2008 was vaccinated with a dose of GARDASIL, that she received under the government's free cervical cancer vaccination program. Following the injection, the patient was barely at school for a month when the patient was rushed to the hospital from school. It was reported the patient was "touch and go" for a week and "stared death in the face". The seizures were reported to last for four months. It was further reported that the students tried to trigger her epilepsy like seizures. By whistling suddenly in her ear caused her to fall to the ground and have a fit. Her mother reported that she was called to school probably twenty times in four months. The students also tried to bring on an asthma attack by spraying aerosol in her face. The article mentioned that the patient stood up to the school bullies who hurled verbal abuse and tried to trigger her epilepsy-like seizures and asthma. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354903-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	07-Aug-2009	07-Aug-2009	0	21-Aug-2009	24-Aug-2009	NY	WAES0908USA01951	24-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Grip strength decreased, Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 25 year old female who on 07-AUG-2009 was vaccinated with a dose of GARDASIL (lot# 661766/0652X, dose and route not reported). On 07-AUG-2009, the patient experienced "weakness, numbness and tingling in both of her hands and fingers" after receiving GARDASIL. The physician stated the patient had this reaction "later in the day but on the same day the GARDASIL was given". The patient complained that she was "unable to turn the ignition in her car to start her car". It was unspecified if medical attention was sought. At the time of the report, the patient's status was unknown. Follow up information was received on 17-AUG-2009 from the physician concerning the 25 year old female with no pertinent medical history and no known drug allergies who on 07-AUG-2009 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. No other vaccines were administered on that day. No treatment was sought following the adverse events. The patient called in to office on 10-AUG-2009 to report event. The patient was not recovered as of 10-AUG-2009. The events of "weakness, numbness and tingling in both of her hands and fingers" were considered to be "somewhat" disabling. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354904-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		21-Aug-2009	24-Aug-2009	--	WAES0908USA02263	24-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a nurse practitioner and a nurse concerning one of her patient's friends who on unknown date was vaccinated with the third dose of GARDASIL (LOT # was not provided). After receiving the vaccination, the patient was admitted to hospital. At the time of this report, the patient was still in the hospital with a "serious" condition. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **354905-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Nov-2008	Unknown		21-Aug-2009	24-Aug-2009	FR	WAES0908USA02731	24-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint swelling

Symptom Text: Initial information received on 14-AUG-2009 from the Health Authority (reference number ES-AGEMED-314488343) regarding an 18 year old female who was administered on 17-NOV-2008 a dose of GARDASIL (batch number not reported) by intramuscular route (site of administration not reported). It was reported that after vaccination, in Nov-2008, the patient presented with swollen joints. The patient has not yet recovered. It has been reported that the patient received a dose of GARDASIL (batch number not reported, route and site of administration not reported) on 27-AUG-2008. It has not been reported whether the patient presented or not adverse events after this dose of vaccine. Case reported as serious by the Health Authority with other medically important condition as criteria. Other business partner numbers included: E2009-08023. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 354906-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Jul-2009	28-Jul-2009	1	21-Aug-2009	24-Aug-2009	KY	WAES0908USA02768	15-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Arrhythmia, Blood test, Cardioversion, Chest pain, Dizziness, Dyspnoea, Electrocardiogram, Palpitations, Supraventricular tachycardia

Symptom Text: Information has been received from a registered nurse and a certified medical assistant concerning a 16 year old female with migraine headaches and allergy to cephalosporin who on 27-JUL-2009 was vaccinated with a 0.5 ml IM first dose of GARDASIL (lot no. 661953/1130X). No other vaccines were given that day. Concomitant therapy included ORTHO EVRA. On 28-JUL-2009 the patient stated she developed a rapid heart rate "it feel like it was rushing out of my chest", standing cause her to loose her breath and dizziness. The symptoms continued through the entire day and into the next. On 29-JUL-2009 the patient was seen at emergency room and was diagnosed with supraventricular tachycardia (SVT) with a heart rate of 200 (bmp). The patient was not hospitalized. The patient underwent cardioversion and was released with heart rate in the 90's (sinus rhythm). On an unspecified date, the patient recovered from supraventricular tachycardia. A blood work and a electrocardiogram (EKG) was performed (results not reported). The patient is being followed by a cardiologist and another physician who reported that holter monitor results were "fine." The reporter stated that supraventricular tachycardia was not related to therapy with GARDASIL. Supraventricular tachycardia was considered to be life threatening an other important medical event. A lot check has been initiated. No further information is available. 8/28/09 ER records received DOS 7/29/09. Assessment: Arrhythmia - Supraventricular tachycardia. Patient complains of palpitations and heart racing. Chest pain and difficulty breathing. 10/13/09 ICD-9 Codes received: 427.89 Other specified cardiac dysrhythmia, 780.4 dizziness, 786.05 paroxysmal nocturnal dyspnea, 785.1 palpitations, 785.0 Tachycardia unspecified.

Other Meds: ORTHO EVRA

Lab Data: cardiac monitoring, results were fine; total heartbeat count, 07/29/09, 200, beats per minute; total heartbeat count, 07/29/09, 90, sinus rhythm. At discharge. 8/28/09 ER records received DOS 7/29/09. LABS and DIAGNOSTICS: Pulse 184. CBC

History: 8/28/09 ER records received DOS 7/29/09. Caffeine.

Prex Illness: Migraine; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **354907-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-May-2009	22-May-2009	0	21-Aug-2009	24-Aug-2009	FR	WAES0908USA02807	24-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonic-hyporesponsive episode, Incorrect route of drug administration, Syncope

Symptom Text: This is a case of a misuse (GARDASIL was administered by subcutaneous route when according to the SMPC intramuscular vaccination is indicated). Initial information received on 12-AUG-2009 by the Health Authority (reference number ES-AGEMED-031435340) regarding a 12 year old female who on 22-MAY-2009 was administered a dose of GARDASIL (batch number not reported) by subcutaneous route, site of administration not reported and a dose of TWINRIX (manufactured by GSK) by subcutaneous route, site not reported. According to Health Authority's report narrative the patient suffered a hypotonic-hypoactive reaction. In the adverse event box vasovagal syncope was coded with start date on 22-MAY-2009 and end date on 22-MAY-2009. Case reported as serious by the Health Authority with other medically important condition as criteria. Case is closed. Other business partner numbers included: E2009-07984. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354918-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		21-Aug-2009	24-Aug-2009	FR	WAES0810CAN00139	24-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with the first and second dose of GARDASIL, lot number (s) not available. Subsequently the patient just found out that she is pregnant. Additional information has been received on 10-AUG-2009 from the nurse who reported that the patient experienced a miscarriage and that patient was not being seen at the clinic at this time (no further details available). Upon internal review, miscarriage was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **354927-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Aug-2009	17-Aug-2009	0	21-Aug-2009	31-Aug-2009	WA		01-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0723Y	0	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB286	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pallor, Tinnitus

Symptom Text: 5 min after rec GARDASIL, HAVRIX & VARIVAX inj - pt became pale, lightheaded - nausea ringing in ears - pt laid on exam table recovered.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354932-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Aug-2009	18-Aug-2009	1	21-Aug-2009	31-Aug-2009	SC		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Heart rate increased

Symptom Text: Dizzy, headache, increased heart rate.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354934-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Aug-2009	17-Aug-2009	5	21-Aug-2009	31-Aug-2009	RI		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA	5	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Vasovagal syncope w/in 2 minutes of GARDASIL administration.

Other Meds: None

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354950-2** **Related reports:** 354950-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jul-2009	01-Jul-2009	0	01-Sep-2009	11-Sep-2009	CA		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2929AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainted after receiving GARDASIL and AVENTIS vax. Mother requested reporting. Pt recovered quickly, no residual.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **354962-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Aug-2009	18-Aug-2009	0	21-Aug-2009	31-Aug-2009	VA		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Dizziness, Nausea, Orthostatic hypotension, Viral infection, Vomiting

Symptom Text: Dizziness, nausea, vomiting starting 4-5 hrs after shot and lasting for several days. On 8/21/09, orthostatic hypotension noted, temp 99.2. Viral illness suspected.

Other Meds:

Lab Data: N/A

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 354967-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Jul-2007	24-Jul-2007	0	21-Aug-2009	25-Aug-2009	WI		30-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0187U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Affect lability, Alopecia, Back pain, Demyelination, Disturbance in attention, Dizziness, Dry eye, Dyspnoea, Extraocular muscle disorder, Fatigue, Fibromyalgia, Gait disturbance, Gastrointestinal disorder, Headache, Heart rate increased, Hoffmanns sign, Hypoaesthesia, Hypophagia, Immediate post-injection reaction, Initial insomnia, Insomnia, Intervertebral disc protrusion, Livedo reticularis, Muscle spasms, Muscle twitching, Musculoskeletal pain, Nausea, Nuclear magnetic resonance imaging abnormal, Nuclear magnetic resonance imaging brain normal, Pain, Pain in extremity, Paraesthesia, Post lumbar puncture syndrome, Raynauds phenomenon, Reflexes abnormal, Restless legs syndrome, Sensory loss, Spinal haemangioma, Stress, Stress urinary incontinence, Wheelchair user

Symptom Text: Light-headed, dizzy, and nauseous immediately after vaccination. Since vaccination: headache, severe fatigue, numbness/tingling in extremities, sharp lower back pain, shoulder pain, hair-loss, memory 'fog'/concentration difficulties, breathing problems, muscle twitching, leg/arm cramping, insomnia, rapid heart beat, overall soreness, GI problems. 9/28/09 Neurology consult received DOS 2/13/08 to 6/6/2008 Assessment: Fibromyalgia. Restless leg syndrome. Patient presents with chronic lower back pain and paresthesias. Developed numbness and tingling "pins and needles" affecting anterior thighs/lower extremities and upper extremities, also including left hand. Gait affected, using wheelchair. Decreased sensation to light touch, pinprick and vibration right upper and lower extremities. Reflexes asymmetrical. Hoffman sign on right. Involutary loss of urine with activity. Post LP headaches, nausea, not eating or drinking very much. Muscle twitching. Difficulty falling asleep. 9/28/09 Rheumatology consult received DOS 2/15/08 to 2/29/08. Assessment: Likely demyelinating process of unclear etiology. Post lumbar puncture headache. Emotional lability brought on by stress of current illness. Patient c/o "legs falling asleep", lower back pain, "pins and needles" right and left arms. Thinning hair. Atypical Raynaud's symptoms, fingers appear dusky, livedo orver dorsum of hand. Eyes dry. Disconjugate movements extraocular muscles.

Other Meds:

Lab Data: Positive ANA, Postitive EEG. LABS and DIAGNOSTICS: Lumbar Puncture - Normal. MRI Head and Spine - Normal. Somatosensory Evoked Potentials - Abnormal. Visual Evoked Potentials - Abnormal. ANA (+). Sleep Study - Abnormal. MRI Back - heman

History: none. Chronic lower back pain. Seasonal allergies. Bilateral shoulder dystocia as a child. Wisdom tooth extraction. Migraine and tension headaches.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **354969-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Aug-2008	23-Aug-2008	0	22-Aug-2009	27-Aug-2009	CA		02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	U2622AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Altered visual depth perception, Asthenia, Balance disorder, Condition aggravated, Confusional state, Disability, Disorientation, Dizziness, Epistaxis, Fall, Fatigue, Gait disturbance, Headache, Injection site pain, Movement disorder, Nausea, Pain, Pain in extremity, Visual impairment

Symptom Text: From the time of vaccination until about a month after, I experienced moderate pain in my left arm at the injection site and in the entire arm and had pain when trying to move it. By that time, school had started on Sept 26, and over the course of the next few months and to the present I began to (and still) experience weakness, dizziness, and fatigue, sometimes with episodes of confusion or disorientation. No matter how much rest or sleep I get, I still experience those symptoms. Also during this same time period, I began to get chronic headaches that varied in severity and struck suddenly during everyday activities. I know for a fact that the headaches were neither due to dehydration or heat stroke because I drink 2 liters of water daily and it was the winter season. In late 2008, around early December, I began to notice something off in my vision. It seemed that when I looked at straight lines, like edges of a wall or a doorframe, etc, the surfaces seemed to shake. All of my symptoms persisted into the new year and the dizziness and vision problem worsened. During January 2009, I started to become so dizzy that it began to affect my balance. I would start stumbling or have errors in depth perception and walk into walls or other solid objects. The vision problem, after doing some online research, I believe is a condition called nystagmus, started to affect not just straight-line figures in my vision, but all shapes and figures. Soon I was seeing my entire environment seem like it was all vibrating or oscillating from side to side or up and down very rapidly. These symptoms, along with the dizziness continued up until February 27, 2009. On the morning of Feb 27, at 8:00a I had just woken up and started to brush my teeth when blood started streaming out of my nose. I hadn't irritated my nose by blowing it or picking it and my nose wasn't too dry either. It was a completely random occurrence. It just started bleeding and it wouldn't stop. Within five minutes' time so much blood had flowed out that it was all over

Other Meds:

Lab Data: Upon arriving at the ER at Medical Center, prior to seeing the doctor, the nurse took my vitals and noticed that one of my pupils were slightly dilated. I saw the doctor and he ordered labs and brain scans. After a CT, lumbar puncture, and

History: Asthma, seasonal allergies. 9/1/09 ER records received DOS 3/5/09. Allergy to Augmentin. Asthma.

Prex Illness: Moderate pain at injection site

Prex Vax Illns: Pain, dizziness, severe headaches, vision-shaking~HPV (Gardasil)~1~18~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355003-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Aug-2009	21-Aug-2009	0	21-Aug-2009	01-Sep-2009	TX		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1423Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Lip swelling, Oedema peripheral, Rash, Swelling face, Vaccine positive rechallenge

Symptom Text: Rec'd HPV #1 12-16-08- No reaction. HPV#2 2-16-09- 2 wks after- severe abd pain, and facial swelling, lips and extremities swollen, no resp diff., HPV #3 6-16-09- rash on abdomen. 9 days after same reaction. Rx BENADRYL.

Other Meds:

Lab Data: RAST testing for latex- Negative, 6/29/09

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355006-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	18-Aug-2009	19-Aug-2009	1	21-Aug-2009	01-Sep-2009	MN		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	PPV	MERCK & CO. INC.	0468X	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	2	Right arm	Intramuscular	
	FLU	CSL LIMITED	02149211A	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Pyrexia

Symptom Text: Developed fever, pain, redness & swelling at area of injection site day after immunization - treated with MOTRIN & antibiotic.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 355009-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Dec-2008	30-Dec-2008	20	24-Aug-2009	31-Aug-2009	AZ		04-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Constipation, Diabetic ketoacidosis, Fatigue, Headache, Increased appetite, Muscle atrophy, Pyrexia, Thirst, Type 1 diabetes mellitus, Vomiting, Weight decreased

Symptom Text: Diagnosed with Type 1 Diabetes Mellitus 10 days after receiving 3rd dose of GARDASIL vaccine made by Merck. 8/25/09 PCP records rec'd. WCC with no concerns 6/3/08-healthy. HPV#1 given. Returned 12/30/08 with c/o fatigue x several weeks, eating and drinking more than usual and rapid wt loss. Urine (+) for ketones at home. Assessment: Diabetes mellitus. Labs: Urinalysis (+) for protein 30, trace blood, large ketones (160). glucose 1000. BS 358. 9/3/09 Hospital records received DOS 12/30/08 to 1/1/09. Assessment: Diabetes mellitus new onset, Diabetic ketoacidosis. Presented with recent weight loss, increased thirst, increased urination, increased hunger. Generalized weakness, fatigue, headache, fever. Episode of vomiting. Constipation. Decreased muscle bulk.

Other Meds:

Lab Data: 12/30/09 Lab glucose 348; Sodium 136; Potassium 3.5; Chloride 103; CO2 9; Urea Nitrogens 14; Creatinine 1.0. 9/3/09 Hospital records received DOS 12/30/08 to 1/1/09. LABS and DIAGNOSTICS: Home Urine Test - Ketones. Fingerstick blood sugar -

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355019-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	29-Jun-2009	15-Aug-2009	47	24-Aug-2009	02-Sep-2009	IL		25-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Loss of consciousness, Sensory loss

Symptom Text: Right leg had no feeling/wd not support weight. Dizzy/Light Headed. Blacked out. 8/26/09 PCP note received. Pt in for PE on 6/29/09 HPV vax given./pc 9/21/09 Spoke with parent. Still reports some numbness as well as new symptom of twitching of the fingers. Has not seen a physician since the ER./pc ```1/8/2010 ED visit for 8/15/2009 Dx Dizziness-vertigo Patient with c/o's dizziness, dx studies wnl, dc'd home no tx

Other Meds: None

Lab Data: Had EKG; Blood test; Inner Ear, sit, stand tests- Everything came back normal. ```1/8/2010 ED visit for 8/15/2009 Dx Dizziness-vertigo Labs: CBC, CMP, UA and Urine pregnancy test all wnl Dx studies: EKG NSR

History: None ```1/8/2010 ED visit for 8/15/2009 Dx Dizziness-vertigo PMH: None Allergies: NKDA

Prex Illness: None ```1/8/2010 ED visit for 8/15/2009 Dx Dizziness-vertigo

Prex Vax Illns:

Vaers Id: **355028-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	18-Jun-2009	18-Jun-2009	0	24-Aug-2009	25-Aug-2009	WY	WAES0908USA02404	25-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAYB296BA		Unknown	Unknown	
	DTAP	SANOFI PASTEUR	C2826AA		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy, Loss of consciousness, Syncope, Tremor

Symptom Text: Information has been received from a physician and an other medical professional concerning a 13 year old female with no pertinent medical history and no known drug allergies who was vaccinated with the first 0.5ml dose of GARDASIL (Lot#660553/0070X) on 18-JUN-2009 in the right arm. Other vaccines given that day included: HAVRIX (unspecified) (GSK) (Lot#AHAYB296BA) and ADACEL (Sanofi Pasteur) (Lot#C2826AA). There were no other concomitant drugs. On 18-JUN-2009, after receiving the first dose of GARDASIL, the patient's eyes rolled back in her head and she fainted while in the office. While she was unconscious the patient experienced "seizure-like head shaking". The other medical professional said there was nothing definitive in the chart to confirm or negate a seizure, as the physician was in another room when the event occurred, chart showed "seizure-like head shaking". The patient had sought medical attention, in the office. There were no diagnostic tests performed. The patient was not sent to emergency room. There was no treatment required. The event was not disabling. At the time of report the patient's status was recovered. Upon internal review, "seizure-like head shaking" was determined to be an other medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355029-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Aug-2009	08-Aug-2009	0	24-Aug-2009	25-Aug-2009	TX	WAES0908USA02799	17-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Convulsion, Grand mal convulsion, Headache, Injection site erythema, Injection site swelling, Joint range of motion decreased, Musculoskeletal stiffness, Neck pain, Pain, Syncope

Symptom Text: Information has been received from a medical assistant concerning her 15 year old sister with no known drug reactions/allergies and no known pertinent medical history who on 30-AUG-2008 received the first dose of GARDASIL (Lot # 655849/0263U) into the right arm. On 08-AUG-2009 was vaccinated with the second dose of GARDASIL (Lot # 662300/0100Y). Concomitant vaccine included Tetanus toxoid and MENACTRA (Lot # U2662A). The medical assistant reported that after second vaccine the patient experienced injection site swelling and redness. On 11-AUG-2009, in the afternoon, the patient fainted on the sports field (according to the medical assistant the event was not environmentally connected); the syncope was followed by a 30 second convulsion which was witnessed by the coach; when the patient came out of it, she had a pounding headache which lasted a week; patient refused any treatment at the time. The patient saw a neurologist on 13-AUG-2009. On 17-AUG-2009, an MRI of head, MRI of neck and EEG were performed (results not expected until 25-AUG-2009). At the time of reporting the patient was recovering. The patient sought medical attention. Upon internal review seizure was considered to be other important medical event. Additional information has been requested. 8/27/09 Neuro consult received dated 8/13/09 with assessment: Cervicalgia-worsening, Convulsions-new, Headache, worsening. Pt presented after episode of generalized tonic-clonic seizure. Pt also reports daily H/As x 1 year-recently worse, neck and back pain and stiffness. PE (+) for trigger points and mildly decreased ROM of the neck. Sent for testing. PT for neck.

Other Meds:

Lab Data: Unknown Labs and diagnostics: MRI brain WNL. EEG WNL. MRI c-spine with bulging cervical discs

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **355030-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Aug-2009	25-Aug-2009	--	WAES0908USA03124	25-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a respiratory therapist concerning a herself who on an unspecified date was vaccinated with a dose of GARDASIL (Lot not reported) while pregnant (date of last menstrual period was not reported). She delivered a boy on 04-MAY-2009, the boy born with "3 holes in his heart". It was unknown if the patient and her baby sought medical attention. At the time of reporting the baby's outcome was unknown. Upon internal review, "3 holes in heart" was considered to be a congenital anomaly. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP=Unknown)

Prex Vax Illns:

Vaers Id: **355058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	31-Jul-2009	01-Aug-2009	1	24-Aug-2009	01-Sep-2009	SC	SC0920	31-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0491Y	1	Left arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041CA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3012AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Chest pain, Fatigue

Symptom Text: Mother reports fatigue and complaints of chest pain, abdominal pain.

Other Meds:

Lab Data: EKG and Chest X-ray within normal limit results

History: none

Prex Illness: no

Prex Vax Illns:

Vaers Id: **355062-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-Aug-2009	21-Aug-2009	0	24-Aug-2009	01-Sep-2009	MI		02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3030AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1715X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF486AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dyskinesia, Immediate post-injection reaction, Loss of consciousness, Pallor

Symptom Text: Gave vaccines to pt while she was lying flat on the exam table. Approximately 30 seconds later, she passed out and had several jerky upper body movements. She then regained conciousness after about 30 seconds and was pale and slightly clammy. Pulse and B/P were normal.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **355064-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Aug-2009	24-Aug-2009	0	24-Aug-2009	01-Sep-2009	NC		02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Pt became dizzy 20 min. after first Gardasil injection.

Other Meds: N/A

Lab Data: N/A

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355072-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-Aug-2009	23-Aug-2009	2	24-Aug-2009	01-Sep-2009	TX		01-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0869Y	1	Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2925AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B036BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: SWELLING AND REDNESS TO LEFT ARM

Other Meds:

Lab Data:

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: 355073-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Oct-2008	20-May-2009	212	24-Aug-2009	31-Aug-2009	AL		15-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	2	Right arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Anorexia, Anxiety, Body height, Cellulitis, Chills, Cough, Depression, Dermatitis contact, Diarrhoea, Fatigue, Foaming at mouth, Infection, Influenza, Lethargy, Nausea, Night sweats, Pain, Pharyngitis, Pollakiuria, Pruritus, Pyelonephritis, Pyrexia, Rash, Rhinitis, Tremor, Urinary tract infection, Weight decreased

Symptom Text: Long-term chronic nausea, chronic abdominal pain, face rash, anxiety, fatigue, depression, weight loss, loss of appetite, tremors, foaming of mouth...required visits to 3 different doctors with numerous prescription medications ordered with no relief. Additional medical records received 10/8/09 Dates of Service 8/4/08 to 9/2/09. Assessment: Contact pruritus, dermatitis, cellulitis, local infection, pyelonephritis, UTI, Influenza with other respiratory manifestations. Assessment: Presented on 8/4/08 with small red lesions on the left inner buttocks, diagnosed with pruritus, contact dermatitis and cellulitis. On 11/15/08 presented with rash and itching of right inner buttocks; diagnosed with cellulitis and a local infection. 6/17/09, presented with fever, lethargy, chills, lower abdominal pressure, and increased urination; diagnosed with pyelonephritis. Follow up on 6/19/09 c/o nightsweats, right lower quadrant abdominal tenderness; diagnosed with UTI. Seen on 9/2/09 for cough, rhinitis, pharyngitis, fever, diarrhea, body aches and chills; diagnosed with influenza with other respiratory manifestations. Presecibed Tamuflu.

Other Meds: na

Lab Data: urine tests(2x); full blood work (2x), upper/lower GI; stool cultures (2x); CT scan Urinalysis: PH 5.0 (L), Blood 1+ (H), Ketones 1+ (H), Protein trace (6/17/09). WBC 15.4 (H), granulocytes 90.8 (H), Anion Gap 16 (H). UA on 6/19/09: Ke

History: penicillin

Prex Illness: na

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355084-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Aug-2008	01-Dec-2008	105	24-Aug-2009	02-Sep-2009	TX		02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site nodule

Symptom Text: Report by parent of "nodule" developing months after injection (at general vaccine site) - developed sensitivity & darkening. See copy of parent's letter/photo to me.

Other Meds: None

Lab Data: Seen by dermatologist - elsewhere

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **355085-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Aug-2009	17-Aug-2009	7	24-Aug-2009	02-Sep-2009	CO		28-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	2	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2913AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT C-reactive protein increased, Chills, Cough, Dysstasia, Gait disturbance, Hypoaesthesia, Joint sprain, Myalgia, Nasal congestion, Nasopharyngitis, Pain in extremity, Pruritus, Upper respiratory tract infection, Viral infection

Symptom Text: 4 days after HPV #3 and MENACTRA leg pain - left upper only - more muscular than bony, increased CRP difficulty walking, missed day of school. 9/23/09 PCP records received DOS 8/10/09 to 8/30/09. Patient presents with c/o numbness right knee. Tender to touch, hard to walk, stand. Antalgic gait. Skin itchy on buttocks. Cold with chills, stuffy nose, cough. DX: URI with limb pain. Leg myalgia. Cough-viral process.

Other Meds: None

Lab Data: CK fractionated, CBC, aldolase, ESR all nl; CRP 1.2. LABS and 9/23/09 PCP records received DOS 8/10/09 to 8/30/09. DIAGNOSTICS: CBC - ABS Lymphocytes 945 Cells/MCL (L). CRP 1.2 MG/DL (H)

History: None. 9/23/09 PCP records received DOS 8/10/09 to 8/30/09. URI, Strep Pharyngitis, Menorrhagia, Sinusitis, Chickenpox.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355088-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Aug-2009	19-Aug-2009	0	24-Aug-2009	02-Sep-2009	AZ		02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0082Y	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain

Symptom Text: Sudden onset left sided chest pain and pleurisy like symptoms approximately 4 hrs after vaccine.

Other Meds:

Lab Data: CXR normal, CBC normal; EKG rhythm NL

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Aug-2009	12-Aug-2009	1	25-Aug-2009	02-Sep-2009	NC	NC09036	02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Fatigue, Headache, Rash

Symptom Text: Rash on legs. One leg shape of a triangle. Having HA's and abdominal cramping, fatigue.

Other Meds: None

Lab Data:

History: 1-7-08- Allergic / 12-13-05 allergic Rhinitis

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355128-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-Nov-2007	01-Jun-2009	578	25-Aug-2009	26-Aug-2009	FR	WAES0908KOR00012	26-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical conisation, Cervical dysplasia, Cervix carcinoma stage 0, Cervix inflammation, Condition aggravated, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 26 year old female with papilloma viral infection (Type 16, 58) who in November 2007, was vaccinated with GARDASIL vaccine. In May 2006, the type 16 and 58 of human papilloma virus were detected in the Pap smear result. The patient was vaccinated with the first dose of GARDASIL in November 2007, the second dose of GARDASIL in January 2008, and the third dose of GARDASIL in May 2008. In January 2009, the patient was diagnosed with the cervical intraepithelial neoplasia (CIN) phase I. In June 2009, the patient was diagnosed with the cervical intraepithelial neoplasia (CIN) phase II. This patient was referred to another hospital for the operation of the cervical conization (It was not reported that the patient received the conization). The reporting physician felt that cervical intraepithelial neoplasia was not related to therapy with GARDASIL vaccine. On 13-AUG-2009 the additional information has been received from a physician via the company sales representative. In May 2006 the patient received the Pap smear test, and the result was the class II (inflammation) and type 16 and 58 of human papilloma virus were detected. In May 2007 the patient received the Pap smear test, and the result was the class III (Cervical low grade intraepithelial lesion) and type 16 and 58 of human papilloma virus were detected. In January 2009 the patient received the Pap smear test again, and the result was the class II (inflammation). In June 2009 the patient received the Pap smear test again, and the result was the class IV. The patient was diagnosed with cervical carcinoma in situ. The reporting physician felt that cervical carcinoma in situ was not related to therapy with GARDASIL vaccine. The cervical carcinoma in situ was considered as other medically important event. No further information is available.

Other Meds: Unknown

Lab Data: cervical smear, ??May06, Pap smear: class II (inflammation); cervical smear, ??May07, Pap smear: class III (cervical low grade intraepithelial lesion); cervical smear, ??Jan09, Pap smear: class IV (cervical carcinoma in situ)

History:

Prex Illness: Papilloma viral infection; Cervical low grade squamous intraepithelial lesion

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355130-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Jun-2009	27-Jun-2009	1	25-Aug-2009	26-Aug-2009	FR	WAES0908USA02729	26-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ28270	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, Hyperventilation, Hypoaesthesia, No reaction on previous exposure to drug, Paraesthesia

Symptom Text: Information has been received from a Health Authority (ref # DK-DKM-20092358) concerning a 12 year old female patient who was vaccinated with the second dose of GARDASIL (IM, batch # MK14370; Lot # NJ28270; site of administration not reported) on 26-JUN-2009. On 27-JUN-2009, eight hours later, the patient was admitted to the hospital with dyspnoea, hyperventilation, tingling sensation and numbness in fingers. The patient recovered and was discharged from the hospital after 10 hours of observation. Electrocardiogram (EKG) performed at the hospital was normal (no further specified). The patient was vaccinated with the first dose of GARDASIL (IM, batch # and route of administration not reported). No adverse reaction was reported. Case is closed. Other business partner numbers include: E200908022. No further information is available.

Other Meds: Unknown

Lab Data: electrocardiogram, 27?Jun09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355136-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Aug-2007	29-Jul-2009	712	25-Aug-2009	31-Aug-2009	NC		01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Hallucination, Menstrual disorder, Sleep disorder, Visual impairment

Symptom Text: She was seeing black shapes, said it was trying to kill her, refused to go to sleep, said if she did she wouldn't wake up, she was put in hospital for 7 days, is on LEXOR 10 mg and SEROQUEL 100mg at night. Between patient's first and second shot, her stomach hurt a lot, after the 2nd shot her period messed up so bad that the doctor had to put her on ORTHOTRICYCLEN for that, and wrote the rest on the main paper. Dates of shot's 8-17-07 -10-12-07 - 2-13-08 could not get lot number.

Other Meds:

Lab Data: Depression - anxiety disorder

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **355139-1 (S)** **Related reports:** 355139-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-May-2008	01-Sep-2008	96	25-Aug-2009	31-Aug-2009	LA		11-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	0	Right arm	Intramuscular	
	TTOX	SANOFI PASTEUR	1010116		Left arm	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Anaemia, Asthenia, Autoimmune disorder, Bundle branch block, Drooling, Dysphagia, Eyelid ptosis, Fatigue, Lip disorder, Myasthenia gravis, Plasmapheresis, Speech disorder, Swollen tongue, Thymectomy, Tonsillectomy, Urinary tract infection, Weight decreased

Symptom Text: Daughter was given two injections of GARDASIL and shortly after was diagnosed with auto immune disease MG which means grave muscle. She has had surgery to remove thymus but still has not recovered. She can not do sports, speak clearly or swallow well. May or may not recover. She never had any prior health problems. 8/27/09 Hospital records received DOS 2/23/09 to 2/28/09. Assessment: Myasthenia gravis, post total thymectomy. Patient c/o of trouble with swallowing and speech articulation unrelieved by tonsillectomy. Weight loss. Ptosis. Generalized weakness. Dx'd with myasthenia gravis. Plasmapheresis. Presents for thymectomy to alleviate symptoms. Urinary tract infection. ICD-9 Codes: 358.00 Myesthenia Gravis, 599.0 Urinary Tract Infection, 425.3 Other Left Bundle Branch Block, 285.9 Anemia unspecified. Follow-up: Sept 2008 - tongue swelling, hypernasal speech. Oct 2008- tonsillectomy. Dec 2008- Drooping lower lip / lack of gag reflex disarthric speech. ```12/17/09 Received Neuro medical records of 2/12/09- FINAL DX: myasthenia gravis Records reveal patient w/drooling, speech difficulties, ptosis, fatigue. Good response to Mestinon.

Other Meds:

Lab Data: 8/27/09 Hospital records received DOS 2/23/09 to 2/28/09. LABS and DIAGNOSTICS: CBC - RBC 4.00 m/uL (L) MCV 90.3 fL (H). CHEM - Anion Gap 16 mEq/L (H) Alkaline Phos 36 U/L (L) LDH 253 U/L (L). Urinalysis - Leukocyte Esterase trace, Bacteri

History: None ```12/17/09 Received medical recors w/PMH: tonsillectomy Family hx: parent w/ITP

Prex Illness: None

Prex Vax Illns:

Vaers Id: **355139-2** **Related reports:** 355139-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-May-2008	01-Sep-2008	96	23-Sep-2009	05-Oct-2009	LA		05-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U		Right arm	Intramuscular	
	TTOX	SANOFI PASTEUR	NULL		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Areflexia, Dysarthria, Myasthenia gravis, Speech disorder, Swollen tongue, Tonsillectomy

Symptom Text: Sept 2008 - tongue swelling, hyper nasal speech. Oct 2008 - tonsillectomy. Dec 2008 - drooping lower lip / lack of gag reflex disarthric speech. Dec 2008 - diagnosed - myasthenia gravis.

Other Meds:

Lab Data: Records sent to VAERS on 8/31/09.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355140-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	18-Aug-2009		25-Aug-2009	31-Aug-2009	AL		06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Complex partial seizures, Convulsion, Fall, Headache, Nausea, Syncope, Vomiting

Symptom Text: This year my daughter and two of my nieces received the GARDASIL vaccine. All three have in the past two months been hospitalized with seizure like symptoms but cause cannot be found. I read the side effects on the website today when I realized they had the shot in common. Today my daughter was injured by falling head first in a busy parking lot and received minor injuries. I this vaccine is causing this problem in girls, it needs to be taken off the market. 10/2/09 Medical records received for date of service 9/2/09. DX: Syncope, Favor Partial Complex Seizure Disorder, Recent HPV Immunization series completion. Presented to ER for syncopal episode prior to this episode felt lightheadedness. Pt was unconscious for 1-2 minutes, nausea and vomiting x2 weeks, headaches. Pt. stated syncopal episode 2 weeks prior and headaches daily since that episode as well as (+)vomiting a few times over past 2 weeks. Completed HPV series 3/09.

Other Meds:

Lab Data: 10/2/09 Medical records received for date of service 9/2/09 Diagnostics/Labs: CT, EKG, CXR Normal. CBC w/diff- monocytes 12.4(H)

History: 10/2/09 Medical records received for date of service 9/2/09 PMH: none

Prex Illness:

Prex Vax Illns:

Vaers Id: 355141-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Oct-2007	01-Jan-2008	69	25-Aug-2009	26-Aug-2009	--	WAES0908USA03209	03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Decreased appetite, Ear discomfort, Ear pain, Headache, Mobility decreased, Nausea, Otitis media, Pain, Pelvic pain, Rhinorrhoea, Screaming, Sinus congestion, Sleep disorder, Tinnitus, Tympanic membrane disorder, Vomiting

Symptom Text: Information has been received from a nurse concerning her approximately 14 year old granddaughter with no pertinent medical history and no known allergies, and a family history of paternal Aunt with cervical cancer and paternal grandmother with cervical cancer who in late 2007 was vaccinated with the first dose of GARDASIL (lot number not reported). On an unspecified date the patient was vaccinated with the second dose of GARDASIL (lot number not reported). In June 2008 or July 2008 the patient was vaccinated with the third dose of GARDASIL (lot number not reported). There was no concomitant medication. 2 or 3 days after the first dose, the patient started having headaches. The headache increase after the second dose was given. The patient was put on NAPROSYN to help the headache (start date not reported0. The headache was worse after the third dose. On an unspecified night the patient woke up screaming at 2 am because of a headache. The patient was sent to the emergency room. No lab diagnostics studies were performed. The patient was put on PERCOCET (start date not reported). There have been times when the patient was throwing up and couldn't get her head off the pillow. The headaches have gotten worse and worse to the point of making the patient nauseous. It was noted that when the headache gets real bad the patient can't get out of bed. 3 months after the third dose, the patient developed ringing of the ear. The nurse felt that the ringing in the ear experienced was associated with the headaches. At the time of the report, the patient had not recovered. It was noted that the patient's father's sister and the patient's father's mother had cervical cancer. The headache was considered to be disabling by the nurse. Additional information has been requested. 9/2/09 ER records from 2 visits 4/17/09 and 5/2/09 received with dx: Serous Otitis and Vomiting/H/A. Pt initially presented 4/17/09 with c/o ear pain, ringing and fullness x 3 days. Recent ear injury. L TM bulging. Tx: nasal spray. Returned 2 weeks later

Other Meds: None

Lab Data: None Labs and diagnostics: pelvic US WNL

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355142-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		25-Aug-2009	26-Aug-2009	HI	WAES0908USA03257	26-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning a female who a couple of years ago was vaccinated with 0.5 ml of GARDASIL (Lot # was not provided). The patient developed Lupus after receiving GARDASIL. No dosing information was provided. The outcome of the patient's Lupus was unknown. The patient sought unspecified medical attention. Upon internal review, Lupus was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355149-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Aug-2009	17-Aug-2009	2	25-Aug-2009	02-Sep-2009	CA		02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	2918AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0381	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Body temperature increased, Headache, Pain in jaw

Symptom Text: Approximately 38 hrs after administration of MENACTRA and HPV vacc, pt developed and was woken by "severe" headache, T 102 degrees, jaw/hand/neck pain. Pt w/ hx URA. Rx ibuprofen. Joint pain improved in < 48 hours fever decrease in < 48 hours.

Other Meds:

Lab Data: None

History: Pauciarticular JRA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355205-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	11-Aug-2009	11-Aug-2009	0	25-Aug-2009	02-Sep-2009	MA		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Myalgia

Symptom Text: Erythema induration right deltoid. Myalgias.

Other Meds:

Lab Data: None

History: Congenital heart condition

Prex Illness: None

Prex Vax Illns:

Vaers Id: **355217-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Aug-2009	24-Aug-2009	0	25-Aug-2009	03-Sep-2009	MI		03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3058AA		Unknown	Intramuscular	VARCEL
	MNQ	SANOFI PASTEUR	U2826CA		Unknown	Intramuscular	
	HEPA	MERCK & CO. INC.	1127Y		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Nausea, Pallor, Syncope

Symptom Text: 3 minutes after client received5 vaccinations she became diaphoretic, pale, nauseated, faint, this continued for about 15 minutes, kept for observation with comfort measures for 35 minutes

Other Meds: No

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **355225-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Aug-2009	21-Aug-2009	2	25-Aug-2009	27-Aug-2009	VA		27-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	UNKNOWN MANUFACTURER	UNK	5	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	UNK	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Postnasal drip, Pyrexia, Upper respiratory tract infection

Symptom Text: Pt. received her Adacel booster and 1st dose of Gardasil on Wednesday August 19, 2009 @ the Health Department. She began to ran a temp of 104.8 on Friday, August 21,2009. She ran a temp of 103 in the early morning of Saturday, August 22, 2009. She came to our practice, and was seen by Dr. Her symptoms consisted of mild URI symptoms, purulent PND, as well as the high fevers. He treated her with a ZPac as well as encouraged patient to rest and take in plenty of fluids.

Other Meds:

Lab Data:

History: None listed

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355228-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	24-Aug-2009	24-Aug-2009	0	25-Aug-2009	03-Sep-2009	CA		03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	UF455AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2918AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Swelling, Tenderness

Symptom Text: redness, swelling and tenderness of the left deltoid

Other Meds: none

Lab Data: None

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355229-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Jun-2007	26-Jul-2007	29	25-Aug-2009	31-Aug-2009	FL		13-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0523U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	NULL	0	Right arm	Unknown	
VARCEL	UNKNOWN MANUFACTURER	NULL	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Anal spasm, Anxiety, Asthenia, Diarrhoea, Eosinophilia, Eructation, Fatigue, Gastritis, Nausea, Oropharyngeal pain, Pallor, Presyncope, Reflux oesophagitis, Vomiting, Weight decreased

Symptom Text: Severe Gastritis, weakness, wt. loss.Nausea, vomitting ,diarreha, anal spasms, vagal reflex responses, & paleness. 9/17/09 GI Consult records DOS 10/4/07 to 6/12/09 Assessment: Reflux Esophagitis. Eosinophilia. Patient presents with abdominal pain followed by diarrhea. Loose, watery bowel movements. Cramping, weight loss, burping, anxiety, sore throat, fatigue, reflux esophagitis. 10/12/09 ICD9 codes received for date of service 6/25/09: 789.09, 535.10, 787.91

Other Meds: none

Lab Data: Endoscopy,colonoscopy, multiple stool specimens, blood tests ,Ct scans,& x-rays. LABS and DIAGNOSTICS: Endoscopy EGD with biopsies, colonoscopy with biopsies - abnormal. CBC - HGB 15.4 g/dL (H) Eosin 24% (H) Eosin 2.1 x10E3/uL. UIBC 140 u

History: 8/31/09 PCP Note DOS 2/9/07. Fever, nausea. Cough. Oropharynx erythematous. Flu-like illness. WBC count 3.5 (L).

Prex Illness: none

Prex Vax Illns: none~ ()~~0.00~Patient

Vaers Id: **355240-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Aug-2009	18-Aug-2009	7	25-Aug-2009	02-Sep-2009	CA		04-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia, Immunisation reaction, Muscular weakness

Symptom Text: Pt had reaction after giving HPV vac. Pt complain of having headaches, dizziness, numbness on L arm and weakness on both legs. Pt was seen by Dr. on 8/18/09. 9/3/09 PCP medical records received DOS 4/1/08 to 8/18/09. Patient does not feel good. Dizziness, weakness, numbness.

Other Meds: PPD

Lab Data:

History: 9/3/09 PCP medical records received DOS 4/1/08 to 8/18/09. Acne, myopia.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355251-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Aug-2009	18-Aug-2009	0	27-Aug-2009	08-Sep-2009	SD		08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure increased, Chest pain, Dizziness, Heart rate decreased, Hypoventilation, Memory impairment, Oxygen saturation normal, Pallor, Pharyngeal hypoaesthesia, Throat tightness, Unresponsive to stimuli

Symptom Text: CNP present after incident. 1550- Became pale, lightheaded - became unresponsive immediately following injection . Assisted with lowering head to knees (pt was sitting in chair). Pulse present, resp shallow. After approx 10 sec, opened eyes agreed to being ok. 1600 - B/P 104/68 P-72 - R 28 . Didn't become clammy. Denies nausea 0/0 dizziness. "Chest hurts - 1605 - BP 118/70 - 1610 HRT R 24 - Recalls little. 1630 Attempted to leave clinic with mother - very vague - c/o tight - numb throat Resp 28 - Began breathing in paper sack - feels better. 1640 - feels better O2 sat 99%. Left with mother. Instructed to go to ER if doesn't improve.

Other Meds: No

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **355254-1** **Related reports:** 355254-2; 355254-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Aug-2009	11-Aug-2009	0	25-Aug-2009	31-Aug-2009	FL		15-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2926AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0216Y	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Conversion disorder, Dizziness, Fatigue, Heart rate increased, Hypoaesthesia, Mental status changes, Palpitations, Tremor

Symptom Text: As per patient - 2hrs after vaccines - developed numbness in arms, hands, felt lightheaded and heart rate speeding. Rescue was called and taken to ER. Few days later (4) Pt confirmed with "problems" and was hospitalized x 48 hours. 9/9/09-ICD-9 codes received 780.4. 785.1. 780.97. 9/9/09-ED report received presented om 8/11/09 with C/O feeling tired and dizzy, improving upon arrival to ED. Observed by parent to have tremors and when assessed without parent present, completely normal. Clinical impression acute dizziness. Palpitations. Altered mental status. Histeria.

Other Meds: PPD

Lab Data: In ER and Hospital. 9/9/09-records received-CT normal.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **355254-2 (S)** **Related reports:** 355254-1; 355254-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Aug-2009	11-Aug-2009	0	23-Sep-2009	24-Sep-2009	FL	WAES0909USA01973	24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Heart rate increased, Hypoaesthesia, Laboratory test, Tuberculin test

Symptom Text: Information has been received from a physician concerning a 15 year old female with a diagnosis of anxiety on 10-JUN-2009, no drug allergies and no other medical history, who on 11-AUG-2009 was vaccinated with her first dose of GARDASIL (IM, lot # unspecified). Suspect therapy included MENACTRA. There was no other concomitant medication. Two hours after the vaccination, the patient developed numbness to her arms and hands, lightheadedness and increased heart rate. Several hours after the symptoms began the patient was taken to the emergency room (name of hospital was not specified) by squad. The patient was released home from the emergency room. A few days later the symptoms continued and the patient was hospitalized for 48 hours (diagnosis not specified). The patient had been in the physician's office for follow up appointments on 12-AUG-2009, 20-AUG-2009 and on 10-SEP-2009. Labs and diagnostic tests included PPD skin test on 11-AUG-2009. Tests were completed (types of tests and results were not specified). At the time of the report, the patient had recovered (date unknown). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Anxiety

Prex Vax Illns:

Vaers Id: **355254-3 (S)** **Related reports:** 355254-1; 355254-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Aug-2009	11-Aug-2009	0	07-Oct-2009	08-Oct-2009	--	200904120	24-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2926		Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Anxiety, Condition aggravated, Dizziness, Heart rate increased, Hypoaesthesia, Incoherent, Insomnia, Lethargy, Nuclear magnetic resonance imaging brain normal, Tuberculin test negative

Symptom Text: Initial case received from a physician, via another manufacturer (WAES 0909USA01973), on 28 September 2009. The following is verbatim from that report: "Information has been received from a physician concerning a 15 year old female with a diagnosis of anxiety on 10-JUN-2009, no drug allergies and no other medical history, who on 11-AUG-2009 was vaccinated with her first dose of GARDASIL (IM, lot # unspecified). Suspect therapy included MENACTRA. There was no other concomitant medication. Two hours after the vaccination, the patient developed numbness to her arms and hands, lightheadedness and increased heart rate. Several hours after the symptoms began the patient was taken to the emergency room (name of hospital was not specified) by squad. The patient was released home from the emergency room. A few days later the symptoms continued and the patient was hospitalized for 48 hours (diagnosis not specified). The patient had been in the physician's office for follow up appointments on 12-AUG-2009, 20-AUG-2009, and on 10-SEP-2009. Labs and diagnostic tests included PPD skin test on 11-AUG-2009. Tests were completed (types of tests and results were not specified). At the time of the report, the patient had recovered (date unknown)." Follow-up information has been received from an office manager in the physician's office indicating that the patient received her first dose of GARDASIL (Lot number 663451/0216Y) on 11-AUG-2009 in her right arm. Suspect therapy included MENACTRA (Lot number U2926) in the left arm." "The PPD testing result was negative. It was reported that the patient had incoherent speech on 11-AUG-2009." "On 14-AUG-2009, the patient went to the ER (Hospital name not reported) for right arm numbness, lethargy, insomnia, and amnesia. On 14-AUG-2009, EEG results were normal". "On 27-AUG-2009, the patient was admitted to hospital. The patient was admitted to the Psychiatric Unit". "On 30-AUG-2009, the patient was transferred out of the Psychiatric Unit on to a regular hospital floor". "On 31-AUG-2009, the pa

Other Meds:

Lab Data:

History: Patient had a history of anxiety, diagnosed 10 June 2009; no drug allergies.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355277-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	25-Aug-2009	25-Aug-2009	0	25-Aug-2009	03-Sep-2009	WI		03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Syncope

Symptom Text: Patient experienced fainting, and nausea.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **355417-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Oct-2007	01-Jun-2009	587	26-Aug-2009	27-Aug-2009	FR	WAES0908USA03088	27-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Multiple sclerosis, No reaction on previous exposure to drug

Symptom Text: Case received from the Health Authority on 17-AUG-2009 under the reference number PEI2009017737. Information has been received from a physician concerning an 18 year old female patient who on 27-MAY-2009 was vaccinated with the third dose of GARDASIL (lot#, route and site of administration not reported). In June 2009, the diagnosis of multiple sclerosis was established via cranial and spinal MRI. Other inflammatory nerve diseases were ruled out. The event was considered as life-threatening by the reporter and the patient was admitted to hospital (unspecified). The reporter stated a "persisting damage". Previous two vaccinations with GARDASIL (Dose1: 23-OCT-2007; Dose 2: 21-JAN-2008) were well tolerated. Other business partner numbers included: E2009-08024. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, ??Jun09, multiple sclerosis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 355418-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Aug-2009	06-Aug-2009	1	26-Aug-2009	27-Aug-2009	AZ	WAES0908USA03202	13-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U291944	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0671Y	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0726Y	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness, Fatigue, Headache, Heat exhaustion, Hyperhidrosis, Malaise, Nausea, Syncope, Vertigo, Vomiting

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on 05-AUG-2009 was vaccinated intramuscular with the first and only dose of 0.5ml GARDASIL (lot # 663452/0671Y). Secondary suspected therapy included VARIVAX administered on 05-UG-2009. Other concomitant therapy included ADVAIR and MENACTRA administered on 05-AUG-2009. On 06-AUG-2009 the patient developed exertional vertigo and extreme fatigue. The patient was a Division 1 softball player and she had not been able to participate due to these symptoms. On 18-AUG-2009 the patient had syncope and ended up in the emergency room. she was not admitted. She will be seen in the office on 19-AUG-2009. The patient had sought the physician for medical attention on 11-AUG-2009. The patient had not recovered. The patient's exertional vertigo, extreme fatigue and syncope were considered to be disabling. Follow up information has been received from the physician concerning the 17 year old female patient who on 15-AUG-2009 had concomitantly received the second dose of VARIVAX (LOT# 664701/0726Y) and MENACTRA (LOT # U291944). On 18-AUG-2009, the patient had syncope and was taken to the Emergency room. The patient had a CT scan and laboratory tests. All testing was negative. The patient was not admitted to the hospital. The patient was seen by the physician on 19-aug-2009. The patient complained of nausea, dizzy and light-headedness on exertion. The physician stated that he was going to refer the patient to a cardiologist for evaluation. Additional information has been requested. 9/3/09 Received ER medical records of 8/18-8/19/2009. FINAL DX: dizziness w/evidence of mild heat exhaustion; possible HPV vaccine side effects. Remained stable & d/c to home w/PCP f/u. Records reveal patient experienced dizziness & malaise since vaccines, with nausea & vomiting while playing sports on day of admission. 9/8/09 Received PCP record of 8/19/09 & vaccine records. FINAL DX: syncopy & nausea Records reveal seen in ER w/neg w/u. Recovered. 11/

Other Meds: ADVAIR

Lab Data: computed axial, 08/18/09, negative; laboratory test, 08/18/09, negative 9/3/09 Medical records received w/LABS: CBC, CMP, CT brain WNL. 11/5/09 Medical records received for date 9/18/09 and 10/15/09 Diagnostics: MRI brain(-), EEG(-), bl

History: None 9/3/09 Medical records received w/PMH: right knee surgery. 11/5/09 Medical records received for date 9/18/09 and 10/15/09 PMH: several syncopal episodes till age 8.

Prex Illness:

Prex Vax Illns:

Vaers Id: 355419-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Nov-2007	31-Jul-2009	633	26-Aug-2009	27-Aug-2009	PA	WAES0908USA03204	27-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1210U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Blood product transfusion, Contusion, Haemorrhage, Idiopathic thrombocytopenic purpura

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter who in Summer 2007 was vaccinated with the first dose of 0.5ml GARDASIL. No information was provided for the second dose of 0.5ml GARDASIL. On 06-NOV-2007 the patient was vaccinated with the third dose of 0.5ml GARDASIL. There was no concomitant medication. On 31-JUL-2009 the patient developed "Idiopathic Thrombocytic Purpura". The consumer stated that "when blood passes through the patient's spleen the antibodies are killing her platelets causing massive bruising and internal bleeding". The patient was hospitalized on 31-JUL-2009 for 4 days. The patient's platelet count was back up after hospitalization, but was going back down again. Laboratory included blood work without result. The patient had not recovered. Additional information has also received from a medical assistant reported that the patient was vaccinated with the first, second and third dose of GARDASIL separately on 05-MAR-2007 (lot # 655849/0263U), 06-JUL-2007 (lot# 658100/0525U) and 06-NOV-2007 (lot # 655154/1210U). No other vaccines given concomitantly. In September 2008, the patient was placed on birth control. Information has also been received from a physician reported that in November 2007, the patient's blood work was normal. On 03-OCT-2008, the patient's platelet count was 190,000. On 30-JUL-2009, the platelet count decreased to 21,000 and the patient was hospitalized the next day it's on 31-JUL-2009. The patient was treated with IV immunoglobulin and steroids. Patient was currently on the titrating dose of prednisone. The physician considered the condition to be disabling but not life threatening. The physician dose not know if GARDASIL was the cause of this event. The patient referred to a hematologist. The receptionist of the hematologist reported that their office was not treating the patient so that the patient might have been treated elsewhere. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: hematology, 11/??/07, normal; platelet count, 10/03/08, 190,0; platelet count, 07/30/09, 21,00

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355420-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		26-Aug-2009	27-Aug-2009	--	WAES0908USA03468	27-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a Nurse Practitioner (N.P) concerning a teenager female patient who on an unspecified date was vaccinated with the first dose of GARDASIL. It was reported that the patient had a seizure after GARDASIL was given. It was reported that the patient went to the emergency room, but it was unknown if the patient was admitted to the hospital. The patient was not given GARDASIL in this nurse practitioner's office but this nurse will be following up with this patient next week. It was also reported that the patient had a first appointment scheduled with the Nurse Practitioner sometime next week (date unknown). The Nurse Practitioner stated that she had spoken to the patient's mother who explained that 30 minutes after receiving the first dose of GARDASIL, the patient had a seizure in the parking lot. The outcome of the patient was unknown at the time of the report. Upon internal review seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **355474-1** **Related reports:** 355474-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Aug-2009	08-Aug-2009	1	26-Aug-2009	08-Sep-2009	GA		08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3097AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2868AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration, Injection site pain, Injection site swelling

Symptom Text: Adverse event onset was 8-08-09 - Client noticed a knot and soreness at injection site on (L) arm. By the next day, soreness, swelling, hardness, and vein enlargement were noted at the bend of the arm on the inner aspect. Area today is only slightly swollen, but remains sore to touch. Vein running along the inner aspects of the (L) mid arm is slighly larger and harder than vein in (R) arm. Client has been applying cold compresses and taking OTC pain/inflammatory medication with some noted improvement, but problem is better one day and then worse the next. Client is concerned.

Other Meds: None

Lab Data: None at this time - referred to Urgent Care for evaluation on 8-26-2009.

History: None

Prex Illness: None - Client Denies illness @ time of Vaccination

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355474-2** **Related reports:** 355474-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Aug-2009	08-Aug-2009	1	03-Sep-2009	14-Sep-2009	GA	GA09031	14-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	286BAA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	3097AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Induration, Injection site nodule, Injection site swelling, Oedema peripheral, Pain in extremity, Vasodilatation

Symptom Text: Swelling/knot at injection site the day after injection, this moved to lower inner aspects of arm at bend of arm and continues to be sore, vein enlarged and hard, with small amount of swelling.

Other Meds: None

Lab Data: none at this time

History: None

Prex Illness: None/Denied

Prex Vax Illns:

Vaers Id: **355482-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Jul-2009	11-Aug-2009	12	26-Aug-2009	08-Sep-2009	VA		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthropod bite, Contusion, Fatigue, Lymphadenopathy, Malaise, Nodule, Paraesthesia, Pharyngeal erythema, Presyncope, Streptococcal infection, Syncope

Symptom Text: Initial near syncopal episode at time of vaccination on 7/30/09. Approximatley 8/11/09, she began to have intermittent problems with easy bruising, tingling, 9/25/09 Received PCP medical records which reveal patient in good general health on day of vaccination & had brief vasovagal syncope after shot. RTC 8/28 after symptoms began 8/11/09 of malaise, tiredness, easy bruising & near fainting episodes while driving. Exam revealed shotty cervical lymph nodes, erythematous throat, macular bruising on arms & nodule on right shin. 9/11 labs revealed + strep & had recent tick bite. Tx w/oral antibiotics.

Other Meds:

Lab Data: cbc - WNL; glu 85; ekg: sinus bradycardia; other labs pending 9/25/09 Medical records received w/LABS: (+)ASO

History: History of pyelonephritis 9/25/09 Medical records received w/PMH: pyelonephritis. Allergy: amoxicillin.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 355483-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Sep-2007	15-Oct-2007	41	26-Aug-2009	31-Aug-2009	ND		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2379BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Anxiety, Appendicectomy, Bronchitis, Constipation, Diarrhoea, Dizziness, Drug withdrawal headache, Dysmenorrhoea, Dyspareunia, Dyspepsia, Eating disorder, Eczema, Fatigue, Flat affect, Gastroenteritis, Headache, Injectable contraception, Insomnia, Laparoscopic surgery, Laryngitis, Migraine, Nausea, Oral contraception, Pelvic inflammatory disease, Pharyngitis streptococcal, Phonophobia, Photophobia, Post coital contraception, Productive cough, Pyrexia, Rash, Somnolence, Wheezing

Symptom Text: Severe headaches/migraines which cause sleeplessness, stomache aches, painful menstrual periods, nausea, always tired and feels like sleeping all the time, dizziness, heartburn. Unable to eat certain foods like fast food burgers. Had appendix taken out October 31, 2008 after one week of fevers above 103 for one week and emergency room visits. Finally after one week surgeon looked at records and determined appendix should have been removed one week earlier. 9/29/09 PCP records received DOS 1/5/07 to 8/7/09. Assessment: Transferred migraine, rebound analgesic headache, anxiety. Patient c/o recent headaches. Repeated strep pharyngitis. Plan B emergency contraception. Oral contraception initiated. Flat affect. Anxiety. Pelvic inflammatory disease. Headaches with photophobia and phonophobia. Pharyngitis/laryngitis with productive cough and wheezing. Bronchitis. Dry eczematous rash skin arms and legs. Abdominal pain, diarrhea, constipation. Gastroenteritis. Depo-Provera initiated. Muscle tension headaches. Insomnia. Painful intercourse. 9/29/09 Hospital records received DOS ER 10/25/08 Inpatient 10/31/08. Assessment: Appendicitis. Patient presented with right lower quandrant abdominal pain. Hematuria. Nauseous, vomited. Discharged from ER. Presents several days later with same complaints. Laparoscopic appendectomy. Pelvic inflammation. ICD-9 Codes: 540.9 Acute Appendicitis NOS, 784.0 Headache, 305.1 Tobacco use disorder/depend.

Other Meds: Doxycycline

Lab Data: 9/29/09 PCP records received DOS 1/5/07 to 8/7/09. LABS and DIAGNOSTICS: Rapid Strep Test (+). CBC - WBC 13.0 Thous 10*3/ul(H) MPV 7.3 cu mic (L) Grans 81.1% (H) Lymphs 11.2% (L) ABS Gran 10.6 Thous (H). 9/29/09 Hospital records received

History: allergic to cats. 9/29/09 PCP records received DOS 1/5/07 to 8/7/09. Strep Pharyngitis with fever, nausea and vomiting.

Prex Illness: none. 9/29/09 PCP records received DOS 1/5/07 to 8/7/09. Depression. Allergic rhinitis. Acne.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355485-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	04-Jun-2009	06-Jun-2009	2	26-Aug-2009	08-Sep-2009	VI		08-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	5	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	0571X	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	O571X	0	Right arm	Intramuscular	
FLU	SANOFI PASTEUR	U2759AA	1	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0195Y	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site scar, Injection site vesicles

Symptom Text: mother and client report at this vist (today) that approx. 2 days after the last vaccination (6/4/09), client developed "a bump" with "water" to left arm, posteriorly. this site was site for varicella. Denies "bumps" at other injection sites. Denies other symptoms or problems. now has scar noted to area. soft, nontender today.

Other Meds: NONE

Lab Data:

History: none

Prex Illness: denied

Prex Vax Illns:

Vaers Id: **355489-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Aug-2009	25-Aug-2009	0	26-Aug-2009	27-Aug-2009	IN		28-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3249AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0384U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Depressed level of consciousness, Disorientation, Head injury, Loss of consciousness, Mental status changes, Mutism, Syncope, Tonic clonic movements

Symptom Text: After a few minutes patient lost consciousness; hit head on table ; unable to rouse; phoned 9-1-1 for EMS transport to Hospital;patient remains hospitalized on date of this report ```DC summary and hospital records received 1/21/10 for dates 8/25/09 to 8/26/09. DX: syncope, tonic clonic muscle contractions, altered mental status. CC: pt received vax and 15 minutes later had syncope episode then hit her head. Tonic clonic contractures persisted upon ER arrival. Pt was disoriented Pt appeared to be elective mutism for several hours afterward. Assessment: WNL except neuro exam, not very verbal, withdrawn. Pt returned to baseline status and was stable at dc.

Other Meds: none

Lab Data: 8/26 EEG- pending; CT spine- no fractures; CT head- normal; Hx of back problems/cortisone injections X 1 year ```DC summary and hospital records received 1/21/10 for dates 8/25/09 to 8/26/09. Diag/labs: xray(-), CT(-), electroencephalogram

History: DENIED ```DC summary and hospital records received 1/21/10 for dates 8/25/09 to 8/26/09. PMH: scoliosis, chronic low back pain, allergic reaction causing tonic clonic muscle jerking, dysmenorrhea, irregular menses.

Prex Illness: DENIED

Prex Vax Illns:

Vaers Id: 355494-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	07-Apr-2009	10-Apr-2009	3	26-Aug-2009	31-Aug-2009	CT		04-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Agitation, Alcohol abuse, Anxiety, Attention deficit/hyperactivity disorder, Bipolar disorder, Disorientation, Distractibility, Drug abuse, Hallucination, Irritability, Paranoia, Schizophreniform disorder, Suicidal ideation

Symptom Text: First acute schizophrenic episode (disorentation and hallucinations)occurred 3 days after HPV vaccination. Required hospitalization and continues to need ongoing treatment. Unable to return to school and usual activites. 11/2/09: Hospital Records and Discharge Summary received for dates of service 4/16/09 to 5/4/09. Dx: Schizoaffective disorder, bipolar type, attention deficit hyperactivity disorder, cannabis abuse, alcohol abuse. Assessment: Pt. brought to hospital ED by local police on a certificate of hold after being missing for 1 day and being found wandering, distracted and responding to internal stimuli. She was anxious, irritable and easily agitated. She had stopped taking her psychiatric medications several weeks before. She displayed prominent thought blocking with loose associations and was having visual and auditory hallucinations. With the help of psychiatric medications, by discharge her affect became broader, mood brighter there was no further thought blocking, thought process was more organized, and she was A&O x 3. 11/2/09: Hospital Records and Discharge Summary received for dates of service 6/18/09 to 6/23/09. DX: Schizoaffective disorder, bipolar type, attention deficit hyperactivity disorder. Assessment: Brought to the Hospital ED by police after threatening to shoot herself, though she had no access to a gun. She had stopped taking psychiatric medications 3 days prior. She was intrusive and tried to escape from the ED, so was medicated with good effect. On assessment she was paranoid and guarded, however she denied suicidal or homicidal ideations. Appeared to be responding to auditory hallucinations and other internal stimuli. While hospitalized, her medications were re-started, her thought processes became logical and coherent. She did not appear to be guarded anymore. Her insight, judgment and impulse control were improved and fair at time of discharge.

Other Meds: Trileptal, Concerta

Lab Data: 11/2/09: Hospital Records and Discharge Summary received for dates of service 4/16/09 to 5/4/09. Labs and Diagnostics: CBC-WNL, Urine Drug Screen, Negative. 11/2/09: Hospital Records and Discharge Summary received for dates of service

History: Bipolar Disorder, ADHD, Allergic to Amoxicillin 11/2/09: Hospital Records and Discharge Summary received for dates of service 4/16/09 to 5/4/09. PMH: Drug and alcohol abuse, ADHD, allergy to Amoxicillin. 11/2/09: Hospital Records and Discharge Summary received for dates of service 6/18/09 to 6/23/09. PMH: As above.

Prex Illness: Bipolar Disorder, ADHD

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355513-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Aug-2009	20-Aug-2009	1	26-Aug-2009	08-Sep-2009	NV		08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2919AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1497X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Injection site erythema, Injection site swelling, Nausea, Pain in extremity, Pyrexia, Skin warm

Symptom Text: MENACTRA shot given in LD Wednesday afternoon - that night arm was red & swollen & also still Thursday morning. Thursday night she felt nauseated. Had chills, fever, & pain in arm - it was looking red/purple & felt hot to the touch - she also had a headache. Didn't see a Dr. but felt better Friday morning. Doing good now.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: ~DTaP (no brand name)~UN~0~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355522-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.6	M	20-Aug-2009	Unknown		26-Aug-2009	08-Sep-2009	TX		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X		Left leg	Intramuscular	
	PNC7	WYETH PHARMACEUTICALS, INC	D37052		Left leg	Intramuscular	
	DTAPHEPBIP	GLAXOSMITHKLINE BIOLOGICALS	AC21B209CA		Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: "none reported by parent".

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **355626-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		27-Aug-2009	28-Aug-2009	--	WAES0908USA04182	28-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Headache, Hemiparesis, Neurological symptom

Symptom Text: Information has been received from a cardiac surgeon concerning a female who was vaccinated with a dose of GARDASIL (lot #660618/0572X). Subsequently the patient developed hemiparesis, headaches and "other neurological symptoms". At the time of the report, the patient's outcome was unknown. The cardiac surgeon considered hemiparesis, headaches and "other neurological symptoms" to be were considered to be disabling since they have become longstanding and incapacitating. This is one of several reports received from the same source. A lot check has been requested. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **355627-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jul-2009	Unknown		27-Aug-2009	28-Aug-2009	--	WAES0908USA03811	28-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anogenital warts, Deafness, Deafness unilateral, Tinnitus

Symptom Text: Information has been received from a pharmacist concerning a 17 year old female with unspecified drug reactions/allergies and medical history, who was vaccinated with a third dose of GARDASIL in July-2009 ("6 weeks" since vaccination) (route and lot number not reported). The pharmacist mentioned the patient experienced ringing in the ear, 50% hearing loss in the unspecified one ear and genital warts. At the time of the report the outcome of the patient was not recovered. The patient sought medical attention by visit physician's office. Ringing in the ear, 50% hearing loss in the unspecified one ear and genital warts were considered to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 355629-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Dec-2008	01-Feb-2009	60	27-Aug-2009	28-Aug-2009	--	WAES0907USA00788	28-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Agitation, Anorexia, Asthenia, Balance disorder, Gait disturbance, Headache, Lymphadenopathy, Malaise, Muscular weakness, Nausea, Oropharyngeal pain, Parosmia, Phonophobia, Photophobia, Physiotherapy, Pyrexia, Viral infection, Wheelchair user

Symptom Text: Initial and follow-up information was received from a physician and a cardiac surgeon concerning his 15 year old daughter with no known drug allergies and had no significant medical history who was described as a healthy girl. She was an active flutist, accomplished and participating in an adult orchestra in her hometown, a soccer player and track runner. On 26-AUG-2008, she was vaccinated with first dose of GARDASIL (Lot # 660555/0279X) and her second dose was administered on 03-DEC-2008 (Lot #660618/0572X). There were no concomitant medications or vaccinations. About mid February 2009 she started to develop what seemed at the time like a viral illness with a sore throat, felt unwell, developed a low grade fever and swollen glands. She rapidly progressed to severe headaches which were accompanied by nausea, photophobia, phonophobia, sensitivity to odors and a complete loss of appetite. The patient also developed severe lower limb weakness and balance/gait disturbance. A multitude of testing including two magnetic resonance imaging (MRI's), electromyography (EMG's), neurovascular checks (NVC's) and multiple labs had been unrevealing. She had been out of school since February 2009 with home tutoring. She became interested in nothing but laying on the couch in a dark and quiet room. She had been unable to tolerate her flute, and had no stamina for any activity including soccer and track. On 26-FEB-2009 the patient saw a doctor, to investigate if the patient was experiencing migraine headaches. Standard migraine treatment including IV DEPAKOTE had not been helpful. The patient was also treated with LORTAB and IMITREX which did not help. Her headaches worsened and were described as a 10 out of 10 on the pain scale and she began to have difficulty walking. She was then sent for a neurology consult and was treated with DEPAKENE and ANTIVERT with no effect. The patient had a battery of laboratory testing done (not otherwise specified) which revealed nothing. On 06-MAR-2009 the patient was seen in the Emergency Room (ER)

Other Meds: None

Lab Data: magnetic resonance, 03/18/09, venus and arterial phase which was negative; magnetic resonance, 05?/??/09, negative; electromyography, 05?/??/09, negative; diagnostic laboratory, 05?/??/09, vestibular testing which came back negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 355647-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-May-2008	01-Aug-2008	78	27-Aug-2009	01-Sep-2009	IL		29-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Blood stem cell harvest, Breath sounds abnormal, Chemotherapy, Cough, Decreased appetite, Dysphagia, Dysphonia, Hodgkins disease, Hodgkins disease recurrent, Lymphadenopathy, Mediastinal mass, Nausea, Oropharyngeal pain, Pyrexia, Rhinorrhoea, Vocal cord paralysis

Symptom Text: Developed Hodgkins lymphoma. We diagnosed patient's cancer in August, 2008, and she is continuing chemotherapy. She will have a stem cell transplant too. 9/28/09 Hospital records received, multiple admissions and outpatient visits, DOS 8/22/09 to 9/09/09. Assessment: Hodgkin's Lymphoma stage II-A, bulky disease. Patient c/o "losing my voice'. (L) vocal cord paralysis. Dysphagia. Mediastinal mass. Chemotherapy. Fever. Neutropenia. Radiation therapy. Relapsed with positive B symptoms, mediastinal mass, neck and lung involvement. Cervical lymphadenopathy. Chemotherapy. Nausea, decreased appetite. Throat pain. Lung sounds diminished (R). Dry nonproductive cough and rhinorrhea. Stem cell harvest.

Other Meds:

Lab Data: 9/28/09 Hospital records received, multiple admissions and outpatient visits, DOS 8/22/09 to 9/09/09. LABS and DIAGNOSTICS: Laryngoscopy - Abnormal. MRI - Abnomal. Blood cultures - No growth. Thoracoscopy with Mediastinal Biopsy - Abnormal

History: None. 8/27/09 PCP medical records received DOS 4/16/08 to 5/15/08. PMH: Wart on hand - Histofreezer - Cryosurgery.

Prex Illness: none-preventative

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355677-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Aug-2009	18-Aug-2009	1	27-Aug-2009	14-Sep-2009	VA		14-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	AHAVB787AB	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3016AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	UF460CA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Skin warm

Symptom Text: 18-20 hrs after injection, pt developed redness, swelling, hot to touch on Rt arm. Seen in office on 8-19-09, recommend apply ice, use BENADRYL.

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355681-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Aug-2009	15-Aug-2009	2	27-Aug-2009	08-Sep-2009	VA		08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vomiting

Symptom Text: Received 1st GARDASIL 8/13/09; mom reports 8/15/09 c/o headache lasting 2 days & vomiting. Had fluids & rest, no ER or follow-up visit. Family history of migraines.

Other Meds: None

Lab Data: None

History: None family hx of migraine headache

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355682-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	25-Aug-2009	25-Aug-2009	0	27-Aug-2009	08-Sep-2009	PA		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	500675F		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0087Y		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Few minutes after shots, patient had a brief syncopal episode lasting 30-45 seconds; complete recovery.

Other Meds: PPD; KEPPRA; LEXAPRO; ZONEGRAN; Amityiptyline; YAZ

Lab Data: None

History: Seizure disorder

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355687-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-Aug-2009	21-Aug-2009	0	27-Aug-2009	08-Sep-2009	FL		08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3355AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0249Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Patient had Tdap and GARDASIL then stood up. Was helping sister get shots then felt lightheaded and fainted.

Other Meds: Birth control

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **355701-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Apr-2009	11-Apr-2009	2	27-Aug-2009	08-Sep-2009	PR	PR-09-11	08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2868AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash, Tinea versicolour, Vomiting

Symptom Text: MOTHER REFERS THE PATIENT PRESENTED WITH VOMITING, ITCHING AND RASH IN SKIN WHICH GOT WORSE. THE DERMATOLOGIST DIAGNOSED TINEA VERSICOLOR AND RECEIVED TREATMENT.

Other Meds: ASPIRINE 81mg DAILY

Lab Data:

History: EPSTEIN ANOMALY (HEART MURMUR)

Prex Illness:

Prex Vax Illns: SKIN RASH AND VOMITING~HPV (Gardasil)~1~16~In Patient

Vaers Id: **355702-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Aug-2009	27-Aug-2009	0	27-Aug-2009	08-Sep-2009	NJ		08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336BA	0	Gluteous maxima	Intramuscular	
	HPV4	MERCK & CO. INC.	0702X	1	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bradycardia, Dizziness, Nausea, Pallor

Symptom Text: APPROX. 20 SECONDS AFTER RECVING HPV VACCINE #2 & HEPA #1 CHILD REPORTED FEELING NAUSEA & DIZZINESS, BECAME PALE & BRADYCARDIC AT 45BPM. SYMPS APPROX 10 MIN . SUPINE, & ORAL FLUIDS.

Other Meds:

Lab Data: EKG DONE , REPEAT HR=60,B/P 94/61, RR=18, 02 SAT=100%. (PREV. HX OF DIZZINESS W/ EXERTION) REFERRED TO CARDIO FOR PROLONGED PR INTERVAL

History:

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **355717-1** **Related reports:** 355717-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	22-Jul-2009	24-Jul-2009	2	27-Aug-2009	08-Sep-2009	DE		02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Headache, Inappropriate schedule of drug administration, Nausea, Neck pain

Symptom Text: Patient has had moderate to severe headaches and nausea ,as well neck and upper back pain since her second injection.Patients father is a physician.He has checked for lymnes disease and patient has also been seen by another physician. She was also seen in the ER. She has a appointment with a neurologist next week.

Other Meds: LoEstrin24 Fe, Tindamax

Lab Data: Lymnes titre was equivocal but the Weatern Block was negative. CBC,Sed Rate and CT Scan negative

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355717-2** **Related reports:** 355717-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	22-Jul-2009	23-Jul-2009	1	02-Nov-2009	05-Nov-2009	DE		11-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea

Symptom Text: light headedness, dizzy, nausea head pain began soon after and has been severe and constant to present date

Other Meds: Loesterin 24FE Elmiron Tindamax

Lab Data: MRI/MRA, CT Scan, bloodwork

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 355728-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Nov-2008	28-Nov-2008	0	27-Aug-2009	28-Aug-2009	IL		20-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Dermatomyositis, Dysphagia, Fatigue, Hepatic enzyme abnormal, Hypersomnia, Immune system disorder, Injection site pain, Lymphadenopathy, Muscle fatigue, Myalgia, Oropharyngeal pain, Pain, Rash erythematous, Rash generalised, Rash pruritic

Symptom Text: 1st vaccine: 11/28/08; Rash on hands appeared soon after, seen by Dr. on 12/7/09 for rash; 2nd vaccine: 2/7/09; 3rd vaccine: 5/1/09 followed by extreme tederness at site and muscle fatigue and pain all over body; numerous doctor visits, tests, and muscle bioposies led to diagnosis on 8/6/09 of dermatomyositis by Dr. During this period (11/28/08 - 5/1/09) rashes also appeared on elbows, knees, hips, and face. In looking back over the time period, there appears to be a connection between the vaccinations their impact on her immune system. Medical literature suggests a possible link between Gardasil and juvenile dermatomyositis, a disease that only affects 5 in 1 million people. 9/1/09 PCP medical records received DOS 2/3/09 to 8/19/09. Assessment: Nonspecific liver enzyme elevation. Nonspecific myalgias, joint complaints, possible rheumatological disorder. On 5/1/09 patient presented with complaints of a red, puritic rash. On the dorsum of and fingers of both hands, concentracted around MCP joints. Later complains of achiness and fatigue on arms and legs, sleeping more. Rash on elbows and knee. 1/7/2010 ED records received. Service date 6/29/09. Assessment: Lympahdenopathy, difficulty swallowing. Patient c/o that it is hard to swallow. Cervical lymphadenopathy. Body aches. Myalgia, sore throat, rash.

Other Meds: None prior to 5/1/09

Lab Data: Patient has had numerous blood tests, skin biopsies, muscle biopsies. Muscle biopsy conducted by University of Iowa confirmed diagnosis of dermatomyositis. 9/1/09 PCP medical records received DOS 2/3/09 to 8/19/09. LABS and DIAGNOSTICS: E

History: 9/1/09 PCP medical records received DOS 2/3/09 to 8/19/09. Egg Allergy.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355741-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Jul-2009	01-Aug-2009	1	27-Aug-2009	08-Sep-2009	NJ		25-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration

Symptom Text: Induration of 1 cm diameter at site of injection (induration still present 3 wks later).

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355743-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Aug-2009	25-Aug-2009	0	27-Aug-2009	08-Sep-2009	PA		08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	500675P		Unknown	Unknown	
	HEPA	MERCK & CO. INC.	0604Y	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0087X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Nausea, Syncope

Symptom Text: 1118AM 3 minutes after shots were given, patient felt nauseous, became weak and fainted on the exam table. She responded immediately to ammonia inhalant; her BP 120/76. Ice pack was applied to her head. She was alert in a few minutes sitting up and ready to leave.

Other Meds: LAMICTAL 25mg; PROZAC 10mg daily

Lab Data:

History: Depression

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355744-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Aug-2009	18-Aug-2009	0	27-Aug-2009	08-Sep-2009	WI		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB326AA	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	3087Y	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2991AA	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Syncope

Symptom Text: Pt fainted, subsequent headache dizziness for 1 week (+).

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355830-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Aug-2009	18-Aug-2009	0	28-Aug-2009	31-Aug-2009	PA	WAES0908USA03108	31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	3	Unknown	Unknown	
	TDAP	SANOFI PASTEUR	3068AA		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2866AA		Unknown	Unknown	
	HEPA	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Inappropriate schedule of drug administration, Loss of consciousness, Overdose, Pallor, Syncope

Symptom Text: Information has been received from a physician and a licensed practical nurse concerning an 18 year old female who on 11-OCT-2006, 21-FEB-2007, 21-JUN-2007 and 18-AUG-2009 was vaccinated with her first, second, third and fourth dose of GARDASIL respectively (lot # are 653735/0688F, 655165/1425F, 657868/0523U and 661952/1129X respectively). Suspect vaccination included a second dose of VAQTA (inactive) (dose 2). Concomitant therapy included MENACTRA (lot#U2866AA) and ADACEL (lot # 3068AA). The nurse stated that she did not see the third dose of GARDASIL documented in the patient's vaccination chart. The nurse stated the patient was given the fourth dose of GARDASIL in error. On 18-AUG-2009, after the patient had received the vaccination she felt dizzy and had syncope. The patient had loss of consciousness for about 10 seconds. The patient regained consciousness. The patient was pale, blood pressure 110/70, Oxygen Saturation on room air 98%. Oxygen was administered, Oxygen Saturation increased to 100%. The patient was observed for 30 minutes with blood pressure 102/62. When the patient stood she felt dizzy. The ambulance was notified and the patient was taken to hospital. The patient was not admitted to the hospital. Per the physician the patient had a seizure after the fourth dose vaccination and was taken to the ER, subsequently the patient was fine. Upon internal review, the seizure was determined to be other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Blood pressure, 08/18/09, 110/7; Blood pressure, 08/18/09, 102/6; Arterial blood O2, 08/18/09, 98%; Arterial blood O2, 08/18/09, 100%

History: Syncope

Prex Illness:

Prex Vax Illns:

Vaers Id: 355831-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	12-Jun-2009	21-Jun-2009	9	28-Aug-2009	31-Aug-2009	--	WAES0908USA03802	17-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1674X	1	Unknown	Unknown	HPV4

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Activities of daily living impaired, Chills, Computerised tomogram, Constipation, Contraception, Diarrhoea, Lymphadenopathy, Nausea, Oral contraception, Ultrasound abdomen

Symptom Text: Information has been received from a Nurse Practitioner concerning a 26 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who in February 2009 was vaccinated with the first dose of GARDASIL with no problems reported. The patient received the second dose of GARDASIL at the beginning of June 2009. Concomitant therapy included hormonal contraceptives (unspecified). It was reported that "three or four weeks after dose two", approximately on 21-JUN-2009, the patient developed nausea and abdominal pain. The patient was seen in the office on 29-JUN-2009 regarding her nausea and abdominal pain. An ultrasound, and computed axial tomography of the lower abdominal quadrant were performed (results not provided). It was reported that "a month after the symptoms began", approximately on 21-JUL-2009, the patient had recovered. Nausea and abdominal pain were considered to be disabling. It was reported that the patient missed work for 1 week. Additional information has been requested. 9/14/09 Medical records received DOS 8/25/08 to 8/27/09. Assessment: Abdominal pain. Patient presents with lower right abdominal pain and lymphadenopathy. Chills, nausea, diarrhea, constipation. Oral contraceptives.

Other Meds: Hormonal contraceptives

Lab Data: Unknown. 9/14/09 Medical records received DOS 8/25/08 to 8/27/09. LABS and DIAGNOSTICS: Colonoscopy - WNL. CBC - WNL. CT Abdomen / Pelvis. Urinalysis (-). Pregnancy test HCG Urine (-). Chest X-ray. US Pelvis.

History: None. 9/14/09 Medical records received DOS 8/25/08 to 8/27/09. Acne vulgaris, Acute pharyngitis Streptococcus, Asthma, contact dermatitis, headache, hematochezia, UTI, laceration left thigh. Vertigo. Falls. Folliculitis. Lymphadenopathy.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355832-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Sep-2008	01-Sep-2008	0	28-Aug-2009	31-Aug-2009	IN	WAES0908USA04086	31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy, Horners syndrome, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician concerning an unspecified age female who in "JUN-2007", in "AUG-2007" and in "SEP-2008" was vaccinated with a first, second and third dose of GARDASIL respectively (routes and lot numbers not reported). The physician reported that the patient received her third dose of the vaccine in "September 2008" which was over a year from the time that she received the second dose of the vaccine. The physician then continued that in "December 2008", the patient was diagnosed with "Horner's syndrome" and her one eye started drooping. Physician noted that the mother of the patient wanted to know if her daughter's experience is associated with GARDASIL. At the time of the report the outcome of the patient was unknown. The patient sought medical attention by physician's office. On an unspecified date a magnetic resonance imaging was performed results not reported. Upon internal review, Horner's syndrome was determined to be another important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Magnetic resonance

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **355833-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		28-Aug-2009	31-Aug-2009	--	WAES0908USA04199	31-Aug-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Headache, Nervous system disorder

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with GARDASIL. Subsequently the patient experienced atypical headaches and neurological disorder. The outcome of the patient was unknown. Atypical headaches and neurological disorder were considered to be disabling. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355848-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-Aug-2009	21-Aug-2009	0	28-Aug-2009	08-Sep-2009	CT		09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Pallor, Skin laceration

Symptom Text: Second dose of GARDASIL given to left deltoid muscle along with PPD to forearm. About 5-10 min after shot, became pale fell forward, hit floor, 3 cm laceration to right eyebrow area. Total time she was unconscious was less than one minute.

Other Meds: PREVACID & PEPCID AC

Lab Data: History of anxiety.

History: Gall bladder removed 5/09.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355850-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Aug-2009	24-Aug-2009	0	28-Aug-2009	14-Sep-2009	ME		14-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure immeasurable, Cold sweat, Hyperhidrosis, Malaise, Mydriasis, Pulse pressure decreased

Symptom Text: 8/24/09 around 1:30pm after I gave pt GARDASIL injection, noticed that she wasn't feeling well. I asked if she had had lunch and she said no. I went to get juice & crackers and asked staff to watch her. When I came back she had no BP, pulse was difficult to obtain, eyes dilated, sweating, clammy. We called Dr to come and check her out. Lasted about 15-20 minutes.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **355852-1** **Related reports:** 355852-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Aug-2009	21-Aug-2009	0	28-Aug-2009	31-Aug-2009	WI		01-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2825AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B039AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Crohns disease, Discomfort, Dizziness, Fall, Immediate post-injection reaction, Joint injury, Syncope

Symptom Text: 11:30am-Pt was given Tdap, HPV, & Meningococcal Vaccine while sitting on exam table. Pt stated she felt "lightheaded" following injections and was instructed to lie down, but pt declined. Very shortly after the pt received immunizations, she fainted. As she was moving from sitting to lying down, she actually slumped forward. The drawer holding some books on the exam table was open. She apparently landed onto the drawer first and then rolled off the drawer landing on the floor. The pt awakened immediately upon becoming supine, as Dr. rushed into exam room upon hearing the loud noise. Initially pt denied discomfort but then did discover that she had some discomfort on the dorsal aspect of her R wrist. The pt was observed closely for quite some time and then allowed to sit up. Even when standing after 15-20 min., she was a little lightheaded. Further questioning revealed pt had no PO intake for the entire day. She was given a couple of glass of apple juice and was brought to parent vehicle via wheelchair. Pt mother was instructed to push fluids for remainder of the day and continue to monitor.

Other Meds:

Lab Data: R Wrist x-ray

History: Crohn disease-controlled, pt complains of vomiting approx once daily

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **355852-2** **Related reports:** 355852-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Aug-2009	21-Aug-2009	0	28-Aug-2009	09-Sep-2009	WI		09-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2825AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B039AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Discomfort, Dizziness, Syncope

Symptom Text: 11:30am-Pt was given Tdap, HPV, & Meningococcal Vaccine while sitting on exam table. Pt stated she felt "lightheaded" following injections and was instructed to lie down, but pt declined. Very shortly after the pt received immunizations, she fainted. As she was moving from siting to lying down, she actually slumped forward. The drawer holding some books on the exam table was open. She apparently landed onto the drawer first and then rolled off the drawer landing on the floor. The pt awakened immediately upon becoming supine, as Dr. rushed into exam room upon hearing the loud noise. Initially pt denied discomfort but then discover that she had some discomfort on the dorsal aspect of her R wrist. The pt was observed closely for quite some time and then allowed to sit up. Even when standing after 15-20 min., she was a little lightheaded. Further questioning revealed pt had no PO intake for the entire day. She was given a couple of glass of apple juice and was brought to parent vehicle via wheelchair. Pt mother was instructed to push fluids for remainder of the day and continue to monitor.

Other Meds: MERCAPTOPURINE 50mg daily

Lab Data: R Wrist x-ray

History: Crohn disease-controlled, pt complains of vomiting approx once daily.

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355862-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	24-Aug-2009	24-Aug-2009	0	28-Aug-2009	09-Sep-2009	IA		09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised, Urticaria

Symptom Text: Patient developed hives and itching all over body 30 minutes after HPV vaccine given. Patient called our office and reported this 1-2 hours after hives developed. Spoke with Dr. Duncan, instructed to take benadryl for hives and itching.

Other Meds: Orthocyclen

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355883-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Aug-2009	26-Aug-2009	1	28-Aug-2009	09-Sep-2009	TX		09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0334Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site rash, Injection site swelling, Injection site warmth

Symptom Text: 8/25/2009: VZV#2 given SQ to Right Arm. Patient c/o pain and soreness that night. On 8/26/2009 Patient went to school and started to feel pain to right arm, went to the school nurse in the afternoon with a erythematous rash to right arm, tender to touch and warm to touch. Came to clinic at 3:00 pm to f/u on arm with an erythematous 1" x 1 1/2", slightly raised area noted to right arm. No anbxs given at the time. Was told to f/u in two days and to take Anaglesics as needed for pain. 8/28/09 at 9:00 am, patient f/u with a 5" x 5 1/2" erythematous area to right arm, slightly tender, slightly warm to touch, but no drainage. Rx: Amoxil 500 mg: 2 PO BID X 7 days; Zyrtec one tab daily.

Other Meds: N/A

Lab Data:

History: Not Known

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355884-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	25-Aug-2009	25-Aug-2009	0	28-Aug-2009	09-Sep-2009	AK		18-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	C3098AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Gait disturbance, Muscular weakness, Musculoskeletal stiffness, Myalgia, Pain in extremity

Symptom Text: Pt had a left leg pain withing hours after having the injection (in her arm) and her quadriceps were sore- the next day she felt complete weakness and had to "lock" her knee to walk. Today, 3 days later pain is better, but still walking abnormally. 9/8/09 PCP medical records received DOS 8/25/09 to 8/27/09 Patient c/o of muscle weakness in legs. Difficulty walking. Leg stiff and sore.

Other Meds: nuva ring. Phenteramine.

Lab Data:

History: Poss PCOS, hirsutism, obesity, tobacco abuse, MVP. Appendenctomy.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **355885-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Jun-2007	14-Sep-2007	104	28-Aug-2009	11-Sep-2009	OH		01-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0388U		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Chest discomfort, Chest pain, Cough, Depression, Dizziness, Dyspnoea, Electroencephalogram normal, Epilepsy, Fatigue, Headache, Ligament rupture, Loss of consciousness, Migraine, Nasal congestion, Nasopharyngitis, Oedema peripheral, Palpitations, Petit mal epilepsy, Postural orthostatic tachycardia syndrome, Pregnancy test positive, Presyncope, Somnolence, Staring, Stress, Syncope, Tremor, Unresponsive to stimuli, Vertigo

Symptom Text: between shot 2 and 3 started having chest pains and racing heart. Went to ER. After shot 3 started having daily headaches and blackouts. Mis-diagoned with Epilepy. On Epilepsy medication for 12 months. 8-25-9 diagosed with Postural Orthostatic tachycardia syndrome. ```1/8/10: ED Records received for dates of service 9/14/07. Dx: Chest pain, musculosketal. C/O chest pain, SOB, shakiness, difficulty breathing, HA, nasal congestion, abdominal pain on and off, head cold and coughing. ```1/13/10: Hospital and primary care records received for dates of service 8/4/08 to 2/10/09. Date of service 8/4/08: Presents with recurrent blank staring spells without response, recurrent blackout spells with prolonged sleepiness, tiredness and depression. Mixed type HA including throbbing, migraine and constant high pain HA related to stress. Vertigo. Date of service 11/20/08: Dx ACL ligament tear, lateral meniscus tear. Date of service 2/2/09: Seen for spells of lightheadedness, "seeing black," and being unable to respond as well as staring spells. Diff. Dx: Absence seizures vs. near syncope. Date of service 2/18/08: Assessment: fatigue, headache, dizzy. Date of service 5/8/08: Assessment: HA, dizziness. Date of service 7/7/08: No c/o, well visit. Date of service 2/10/09: Assessment: Chest discomfort, Pregnancy test positive, Syncope. ```records received on 01/28/2010. Discharge summary for 05/31/09-06/01/09. Assessment: Neg. for deep venous thrombosis. Admit for R/O deep venous thrombosis. Pregnant patient (31 wks) presents with c/o L. leg swelling, after a car ride (4.5 hr) earlier today. Examination noted trace pedal edema bilaterally with slight increase in L. lower extremity. Post bilateral lower extremity dopplers, patient discharged home. ```records received on 01/28/2010, Hospital OB/consult records for DOS 07/27/09-07/30/09, clinic rec for DOS 08/28/09-04/02/09. Assessment: Postural orthostatic tachycarida. Spontaneous vaginal delivery of male infant (apgars 8/9) with n

Other Meds:

Lab Data: Chest x-rays/ MRI/ EEG / Echo cardiogram / Tilt Test / ```1/8/10: ED Records received for dates of service 9/14/07. Labs and diagnostics: CXR Negative. UA WNL. Urine HCG-Neg. CT Brain-no acute abnormalities. ```1/13/10: Hospital and p

History: allergic to dust, maple, cock roach. ```1/13/10: Hospital and primary care records received for dates of service 8/4/08 to 2/10/09. PMH: Appendectomy, Allergy to codeine, ADHD, Language deficit disorder.

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355887-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Aug-2009	26-Aug-2009	0	28-Aug-2009	11-Sep-2009	MO		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Developed migrane headache

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355894-1** **Related reports:** 355894-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Jul-2008	08-Oct-2008	78	29-Aug-2009	11-Sep-2009	CA		05-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Convulsion, Dizziness, Fatigue, Loss of consciousness, Postictal state, Syncope, Tonic clonic movements

Symptom Text: fatigue, fainting, dizziness and seizures starting in 10/08 and lasting until seizure were under control in 3/09 while taking trileptal. There were a few fainting spells and over twenty different seizures during the five month period. Seizures started again after second dose of gardasil given in 6/09. 9/15/09 Neurology consult records received DOS 6/10/09. Assessment: Complex partial epilepsy. Patient had episode of loss of consciousness. Passed out 7-8 min w/o postictal period. Recurrent episode with whole body jerking following by 30 min postictal period. Continued recurrent seizures. Episodes are preceeded by chest pain.

Other Meds:

Lab Data: 9/15/09 Neurology consult records received DOS 6/10/09. LABS and DIAGNOSTICS: EEG - ABNORMAL. MRI - Normal. Echocardiogram - Unremarkable. Chest X-ray - Unremarkable. EKG - Unremarkable.

History: 9/15/09 Neurology consult records received DOS 6/10/09. Trauma (L) elbow with surgical fixation.

Prex Illness:

Prex Vax Illns:

Vaers Id: **355894-2** **Related reports:** 355894-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Jun-2009	21-Jun-2009	5	29-Aug-2009	11-Sep-2009	CA		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: fainting, seizure about a week after vaccine given

Other Meds: trileptal for previous seizures that started after first dose and then were under control until second dose.

Lab Data:

History:

Prex Illness:

Prex Vax Illns: fainting, dizziness, seizures~HPV (Gardasil)~1~16~In Patient

Vaers Id: **355895-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Jun-2009	21-Jun-2009	5	29-Aug-2009	11-Sep-2009	CA		05-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: fainting, seizure about a week after vaccine given

Other Meds: trileptal for previous seizures that started after first dose and then were under control until second dose.

Lab Data:

History:

Prex Illness:

Prex Vax Illns: fainting, dizziness, seizures~HPV (Gardasil)~1~16.10~In Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355904-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	27-Jan-2009	Unknown		28-Aug-2009	09-Sep-2009	WA		09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection

Symptom Text: Patient developed ASCUS PAP and high risk HPV detected following 3 GARDASIL vaccines given 2008/2009.

Other Meds:

Lab Data: Pap 8/13/09

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355906-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Aug-2009	18-Aug-2009	0	28-Aug-2009	09-Sep-2009	IA		09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3246BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Loss of consciousness, Nausea, Pallor

Symptom Text: Patient was given ADACEL first without incident pt was then given GARDASIL vaccine and immediately lost consciousness for 2-3 minutes, followed by a 15-20 min duration of pallor, nausea, light headedness. Had pt rest, cool compress to head, given juice and crackers.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355910-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Aug-2009	24-Aug-2009	0	28-Aug-2009	09-Sep-2009	MA		09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	500677P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0087Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Injection site swelling, Lethargy, Nausea

Symptom Text: 8/24 afternoon- pt received vaccines evening- sent by nurse to ER with severe joint pain, nausea and lethargy. 8/25 Pt still in pain and vaccine sites swollen.

Other Meds: None

Lab Data:

History: Penicillin allergy; Lumbar spondylolysis

Prex Illness: None

Prex Vax Illns:

Vaers Id: **355916-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	05-Jun-2009	06-Jun-2009	1	28-Aug-2009	09-Sep-2009	NY		09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B033BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy, Pruritus, Rash erythematous

Symptom Text: When child woke up next morning after getting Tdap & HPV vaccines afternoon before she felt itching on her neck, both sides. Glands felt swollen per child. It itched on neck & top of shoulders for 3-4 days. Red spots on neck (over glands). Went away after 3-4 days.

Other Meds: None

Lab Data: None done

History: No known allergies; No birth defects; No med. condition

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355941-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Aug-2009	17-Aug-2009	0	28-Aug-2009	09-Sep-2009	CO		10-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3247AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0070X	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0805Y	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Skin laceration, Suture insertion, Syncope

Symptom Text: After administration GARDASIL pt was kept for 15 minutes we then proceeded to our check-out desk. She then had a syncopal episode and hit her head as she fell. Two interrupted sutures were placed on to forehead.

Other Meds:

Lab Data:

History: Heart Murmur- benign

Prex Illness:

Prex Vax Illns: Syncope~Varicella (Varivax)~1~15~Patient|Syncope~Tdap (Adacel)~1~15~Patient|Syncope~HPV (Gardasil)~2~15~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **355949-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Aug-2009	18-Aug-2009	1	28-Aug-2009	09-Sep-2009	TX		09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Neck mass, Pain

Symptom Text: Collar bone sore. Bump on left side of neck. C/o of pain with intensity x 2 days.

Other Meds: None

Lab Data: X-ray left shoulder & clavicle

History: cyst rem. left clavicle above noted site 3 years ago

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356006-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Mar-2009	18-Apr-2008	-319	31-Aug-2009	01-Sep-2009	FR	WAES0908USA04442	17-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Vaccine positive rechallenge

Symptom Text: Information was obtained on request by the Company from the agency via a public case details form concerning a 14 year old female patient who on 03-MAR-2009 was vaccinated with the first dose of GARDASIL (Lot number not reported). On 18-APR-2008 the patient experienced a seizure and was hospitalized. On 08-MAY-2008 the patient received the second dose of GARDASIL (Lot number not reported). On 22-MAY-2009, the patient experienced seizure and was hospitalized. On an unspecified date the patient commenced antiepileptic medication. The agency considered that convulsions were "certain" related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 356007-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Nov-2008	01-Nov-2008	0	31-Aug-2009	01-Sep-2009	FR	WAES0908USA04419	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Diarrhoea, Disability, Fatigue, Headache, Malaise, Nausea, Pyrexia, Vomiting, Weight increased

Symptom Text: Information was obtained on request by the company from the agency via a public case detail concerning a 24 year old female patient who on 01-NOV-2008 was vaccinated with a dose of GARDASIL. It was reported that on 01-NOV-2008, after first injection the patient experienced acute fever and nausea (November 2008), and after second injection (December 2008) the patient also experienced acute fever, severe headache, diarrhea, nausea and vomiting. Ongoing fevers, severe fatigue, malaise and relentless weight gain of almost 20 Kg since late 2008. There was symptomatic management. There were extensive pathology investigations performed which included a significant MRI brain (incidental small mass found), chest-X-ray which was normal and CT of abdomen and pelvis which were reported to be normal. It was reported that the patient had not yet recovered. The events of pyrexia, diarrhea, headache, malaise, nausea, vomiting and weight increased were considered to cause incapacity/disability. The agency considered that pyrexia, diarrhea, fatigue, headache, malaise, nausea, vomiting and weight increased were possibly related to vaccination with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, MRI brain, incidental small mass found; Chest X-ray, normal; Abdominal computed axial tomography, normal; Computed axial tomography, pelvis, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 356008-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Mar-2009	15-Mar-2009	14	31-Aug-2009	01-Sep-2009	FR	WAES0908USA04187	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0747X	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anaemia, Asthenia, Histiocytic necrotising lymphadenitis, Histology abnormal, Leukopenia, Lymphadenopathy, Pyrexia

Symptom Text: Case received from the Foreign Health Authorities on 24-AUG-2009 under the reference number S200908-671 and transmitted by the foreign agency. A 25 year female patient received the second dose of GARDASIL (lot # 0747X, batch # NJ40530) via intramuscular route on 01-MAR-2009. On 15-MAR-2009, the patient developed fever during 3 weeks and asthenia during 4 weeks, and on 31-MAR-2009 she developed asthenia, leucopenia and cervical adenopathy during 4 weeks. The histological diagnosis revealed histiocytic necrotizing lymphadenopathy (Kikuchi-Fujimoto disease). The patient was treated with METAMIZOL and PARACETAMOL. She was not taking any concomitant medication at the time of the administration of the second dose of GARDASIL, nor between the date of administration and the occurrence of the adverse reaction. It was unknown whether the patient had a history reaction to other medicine. At the time of the reporting, the patient had recovered. To be noted in the adverse event field, the Health Authorities described the following adverse events: Fever, lymphadenopathy cervical, asthenia, leucopenia, anaemia and Kikuchi disease, by this order. However in the narrative, there was neither information about anaemia nor any dates of the histological diagnosis of Kikuchi disease. Other business partner numbers include E2009-08174. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **356010-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		31-Aug-2009	01-Sep-2009	--	WAES0908USA03993	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Cerebrovascular accident, Dizziness, Gait disturbance, Nerve injury, Syncope

Symptom Text: Information has been received via internet concerning a 16 year old female who on unspecified dates was vaccinated with the first two doses of GARDASIL. Subsequently the patient experienced fainting, stroke, memory loss which was devastating. The patient stated that she could barely walk, she was so dizzy that she would have to just sit down. The patient's mother stated that physician diagnosed her daughter with nerve damage caused by GARDASIL. Upon internal review, stroke was considered an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 356017-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-Jun-2009	27-Jun-2009	7	31-Aug-2009	01-Sep-2009	FR	WAES0908USA03923	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Back pain, Cystitis, Lung disorder, Pyelonephritis

Symptom Text: Initial and follow-up information has been received from Sanofi Pasteur MSD as part of business agreement. Case received from a general practitioner on 20-AUG-2009: A 22-year-old female patient received the first dose of GARDASIL (batch number not reported) on 20-JUN-2009. On 27-JUN-2009, she presented with cystitis, which was treated with MONURIL. On 20-JUL-2009, she complained of lumbar pain. She was given NEXEN, then she was given anti-inflammatories drugs due to stomach pain. She was hospitalized on 26-JUL-2009 during 7 to 10 days. Pyelonephritis and right basal pleuropnemopathy were diagnosed. She was given antibiotics and saw a kinesitherapist. The reporter did not have any other information. She did not know whether an infectious agent had been identified. Other business partner numbers include E2009-08132.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 356026-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Apr-2007	Unknown		31-Aug-2009	01-Sep-2009	AZ	WAES0908USA03159	22-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U1922AB	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0245U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Autoimmune disorder, Complex regional pain syndrome, Dyspnoea exertional, Joint stiffness, Joint swelling, Oedema, Oedema peripheral, Pain, Pain in extremity, Paraesthesia, Vein disorder, Weight increased

Symptom Text: Information has been received from a consumer concerning her daughter (a 15 year old female) with food allergy and asthma "who received all three doses of GARDASIL but received the first dose of GARDASIL in April, 2007. Concomitant therapy included DEPO-PROVERA. Subsequently the patient started to experience severe pain and swelling in her left hand and arm. The patient saw her pediatrician who sent her to a hand specialist and after several visits the patient was given a CORTIZONE shot (manufacturer unspecified) that did not relieve the pain and then she was casted for two weeks and that did not help either, but then the symptoms disappeared. Then in June 2008 the patient woke up and had severe pain and swelling in her right foot. The patient saw her pediatrician who did several X-Rays and blood work and was sent to an orthopedic physician. The orthopedic physician gave the patient another CORTIZONE shot (manufacturer unspecified) but her foot continued to swell to the size of a small football. The patient then continued to have severe pain all over her body and had achy joints. Then in August, 2008 the patient's left foot became swollen with severe pain. The patient was hospitalized for two or three days where they did a lymph scan, bone scan, cardiac series and blood series. The patient then saw a specialist in October, 2008 who diagnosed her with Complex Regional Pain Syndrome, which was an auto immune disease. The consumer reported that the way this syndrome worked was that she went into remission for sometime and then it would come back. The patient still had swollen feet that got very raw and she was given GABAPENTIN (manufacturer unspecified), CYMBALTA (manufacturer unspecified). The consumer reported that the patient saw a Rheumatologist and a pain specialist." Follow up information was received from a Registered Nurse (R.N.) on via telephone. It was reported that the patient received the first (lot# 656050/0245U), second (lot# 657737/0522U) and third (lot# 658560/1062U) dose of GARDASIL on 16-APR-2007,

Other Meds: DEPO-PROVERA, Vicodin.

Lab Data: Unknown. 9/4/09 Hospital records received DOS 8/12/08 to 8/14/08. LABS AND DIAGNOSTICS: MRI Foot (at other facility) - Abnormal, cellulitis. CHEM - CO2 21 mMOL/L (L). Chest X-ray - Normal. Bone Scan Hands and Feet - Normal. Lymphangioscinti

History: 9/4/09 Hospital records received DOS 8/12/08 to 8/14/08. Ovarian cyst - post cystectomy. Appendectomy. Asthma. Allergies to citrus, shellfish, soy, nuts, all fruits.

Prex Illness: Asthma; Food allergy

Prex Vax Illns:

Vaers Id: 356028-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		31-Aug-2009	01-Sep-2009	FR	WAES0906CAN00112	01-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0858X	2	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Bedridden, Chills, Hyperhidrosis, Nausea, Pyrexia, Tremor, Vomiting

Symptom Text: Information has been received from a nurse concerning her daughter who was vaccinated with the third dose of GARDASIL (lot # 0858X) expiry 24-JAN-2010. Subsequently, 48 hours after receiving the third dose of GARDASIL, the patient experienced nausea, vomiting, high fever, chills, shaking and sweating. The patient was treated with ADVIL and GRAVOL. Additional information has been received on 19-AUG-2009 from the nurse concerning her 16 year old daughter. The patient presented with symptoms 48 hours after receiving the vaccine and the mother thought that the patient had come down with a flu bug (viral). The fever was treated with TYLENOL and ADVIL and the nausea was treated with GRAVOL. The patient kept to only fluids for 4 days and literally did not get out of bed for 4 days. On day 6 the patient was at the worse of her symptoms. The reporter felt that nausea, vomiting, high fever, chills, shaking and sweating were related to GARDASIL. Upon internal review, the patient's nausea, vomiting, high fever, chills, shaking and sweating were considered to be disabling. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **356031-1 (S)** **Related reports:** 356031-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Apr-2008	15-Oct-2008	173	31-Aug-2009	08-Sep-2009	OH		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	HPV4

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Pain in extremity, Rheumatoid arthritis

Symptom Text: My daughter had the series of GARDASIL vaccination on 10/3/2007, 12/14/2007 and 4/25/2008. Starting in October, 2008 she started having pain in her feet and by the end of the college year May/June 2009 the pain had spread to her ankle and knee joints. Later in June the pain had spread to all the joints in her body, to the point she had difficulty getting out of bed in the morning. She has since been diagnosed with rheumatoid arthritis. I heard that one of the possible side effects of the GARDASIL vaccinations is auto-immune diseases, so I thought this should be reported.

Other Meds:

Lab Data:

History: 9/1/09 PCP medical records DOS 10/03/07 to 4/25/09. Back Pain, lumbago. Bulging disk and facet inflammation. Plantar wart. Wart removal. Penicillin allergy.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356032-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Jun-2008	21-Apr-2009	306	31-Aug-2009	08-Sep-2009	--		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	10634	2	Left arm	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Dysuria, Kidney infection, Mass, Pollakiuria, Pyelonephritis, Urinary tract infection

Symptom Text: My daughter received all three injections of GARDASIL. Since receiving the last injection, she has been hospitalized with severe kidney infections and now has an odd mass on her head. We are seeing a surgeon on Friday 8/28/09 about removing the the mass on her head. My daughter has NEVER been sick before. She is 14 years old and only became sick since receiving the GARDASIL vaccine. Please help us to put an end to this horrible drug. Thank you. 10/7/09: Vaccine record received for date of service 6/19/08, VAERS updated. 10/26/09: Urgent Care Records received for date of service 6/25/09 and Hospital Records received for dates of service 4/21/09 to 4/24/09. Dx: UTI and Acute R Pyelonephritis. Assessment: Admitted for acute R pyelonephritis on 4/21/09 and started on IV antibiotic therapy. Seen again on 6/25/09 for frequency and burning on urination: UTI, prescribed amoxicillin. ICD 9 Codes: 599.0, 041.02, 706.1, 590.80.

Other Meds:

Lab Data: CAT Scan; Pharmaceutical agents; Hospitalization; Seeing a surgeon 8/28/09. 10/26/09: Urgent Care Records received for date of service 6/25/09 and Hospital Records received for dates of service 4/21/09 to 4/24/09. Labs and diagnosti

History: None. 10/26/09: Urgent Care Records received for date of service 6/25/09 and Hospital Records received for dates of service 4/21/09 to 4/24/09. PMH: Myringotomy tubes, UTI's, acne, on OCP's.

Prex Illness:

Prex Vax Illns:

Vaers Id: **356033-1 (S)** **Related reports:** 356033-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Jul-2009	24-Jul-2009	14	31-Aug-2009	04-Sep-2009	LA	LA090807	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Confusional state, Dizziness, Encephalitis viral, Headache, Lumbar puncture, Musculoskeletal stiffness, Nausea, Neck pain, Photophobia, Similar reaction on previous exposure to drug, Tenderness, Vomiting

Symptom Text: See copies of pt's record 7/31/09. 8/20/09 Spoke by phone to mother of patient says that patient received #1 HPV on 9-19-08. On Oct/2008 patient was hospitalized for 2 mos with S/S like the S/S she had on 7/31/09 but much worse. According to mom, patient was seen at ER on 7/31/09 but not admitted. According to mom, they were told that the episode of what happened to pt. were not for sure if it was related to HPV vaccine. 17 y/o presents with c/o headache which started on Monday and increased in severity to a 7 out of 10 on pain scale. Pt. reports no blurry vision with headache. Pt. reports the headache is on the (L) side of her head and is dull in description. Pt had one episode of N/V yesterday. Pt. reports headache is about 1 out of ten now. Pt. reports neck stiffness since Monday and has increased. Pt. reports tenderness to touch of her upper neck and pain when putting chin to chest. Pt. has had similar episode in Oct. 2008 and was hospitalized for about 1 1/2-2 months with IV antibiotics (ROCEPHIN) & Acyclovir for what appeared to be HSV-1 encephalitis. Pt had CT scans & MRIs which showed some edema & focal enlargement of the right media temporal lobe. Herpes encephalitis was a consideration. Pt. also had started taking ORTHO-TRICYCLEN & GARDASIL 2 wks prior to incident. Pt also reports taking both drugs again for about 2 wks. Pt has recently returned from band camp. ```1/8/2010 MR and Neuro consult notes from hospital admission 10/18/2008, Dx Viral encephalitis patient with c/o's 7 day hx of headache with associated sx of nausea, vomiting, dizziness, photophobia, confusion, LP done, on Acyclovir x 14 days, no DC date given

Other Meds: ORTHO-TRICYCLEN

Lab Data: ```1/8/2010 MR and Neuro consult notes from hospital admission 10/18/2008, Dx Viral encephalitis Labs: CBC, wbc high, CMP wnl, ESR and CRP high, strep test neg, CSf, high wbc, protein and lymphocytes, low rbc and glucose, csf and blood cul

History: No known allergies; No med. condition ```1/8/2010 MR and Neuro consult notes from hospital admission 10/18/2008, Dx Viral encephalitis PMH: none Allergies: NKDA

Prex Illness: None ```1/8/2010 MR and Neuro consult notes from hospital admission 10/18/2008, Dx Viral encephalitis

Prex Vax Illns: yes~HPV (no brand name)~1~16.00~Patient

Vaers Id: **356033-2 (S)** **Related reports:** 356033-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Sep-2008	03-Oct-2008	14	28-Sep-2009	29-Sep-2009	--	WAES0909USA02460	02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Unknown	
	HEP	MERCK & CO. INC.	1622U	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Encephalitis, Headache, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse concerning a 16 year old female patient with no pertinent medical history and no known allergies who on 19-SEP-2008 was vaccinated with the first 0.5 ml dose of GARDASIL (lot number 660553/0070X). Secondary suspect vaccination therapy on the same day included the third dose of RECOMBIVAX HB (lot number 657898/1622U). Two weeks later, on approximately 03-OCT-2008, the patient was hospitalized (name and address unspecified) for two months and was diagnosed with encephalitis. On 10-JUL-2009 the patient was vaccinated with the second 0.5 ml dose of GARDASIL (lot number 659054/0315Y). There was no other vaccination therapy on that day. Concomitant medication included birth control (name and manufacturer unspecified). On 31-JUL-2009 the patient experienced a severe headache and went to emergency room (ER) of a hospital. On 31-JUL-2009 a computed axial tomography (CT) was performed and the result was normal ("no acute process"). The patient was not admitted. There was no encephalitis. The patient did not receive the third dose of GARDASIL. The symptom improved after the vaccination therapy was stopped. At the time of the report, the patient had recovered. The nurse added that the information surrounding the first event of encephalitis and hospitalization following the first dose of GARDASIL was not available; the office found out about the experience directly from the patient in August 2009. The encephalitis was considered to be life-threatening by the reporter. No further information is available.

Other Meds: Unknown

Lab Data: computed axial, 07/31/09, no acute process

History:

Prex Illness: Contraception

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356041-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Aug-2009	26-Aug-2009	2	31-Aug-2009	10-Sep-2009	AZ		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Nausea, Oropharyngeal pain, Pyrexia, Rash pruritic, Sinus congestion, Streptococcal identification test negative

Symptom Text: Developed fever of 100 last night and had left sided abd pain on Wednesday. 8/26/09. Woke up this AM 8/27/09 with rash on back of legs and waist that itch. Today has sore throat and some sinus congestion, some nausea. Strept screen negative. Given topical cream and XYZAL for itching.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356049-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Aug-2009	27-Aug-2009	3	31-Aug-2009	10-Sep-2009	MI		08-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2733AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1487U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adverse reaction, Guillain-Barre syndrome, Injection site pain, Muscle contractions involuntary, Muscle injury, Muscular weakness, Myalgia, Oedema, Oedema peripheral, Pain in extremity, Skin discolouration

Symptom Text: Patient presented in the office on 8/27/09 three days post-administration of Menactra and her first Gardasil with myalgia. She was brought in after extremities experienced a color change while the patient was swimming on 8/27/09. Patient was sent for lab work on 8/27/09. Based on critically elevated CPK, total and CKMB along with symptoms the provider felt this could be a case of Guillain Barres Syndrome. 9/8/09 PCP records received. In for WCC on 8/24/09. Vax given. Pt returned to office 8/27/09 with R arm pain and swelling of the whole arm, muscle soreness and injection site tenderness as well. While swimming, pt's arms and toes turned purple. PE (+) for edema, muscle fasiculations and weakness (Rarm > Left) of the arms, fingers and toes. CPK/CKMB indicative of skeletal muscle damage. Dx: Myalgia. Adverse Reaction. Guillain Barre. Increased CPK. Tx with steroids. Pt has not sought any other treatment at this time.

Other Meds: Concerta

Lab Data: Labs drawn 8/27/2009: CPK 8784; CKMB 31.1; AST 186; ALT 72; Serum Protein 8.9; Serum Albumin 4.7; Globulin 4.2. Patient to repeat lab testing in one week. Labs: UC (+) for E.coli. AST 186. ALT 72. Total serum protein 8.9. Serum albumin

History: PMH: learning disability. menstrual H/A. metabolic syndrome

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Aug-2009	31-Aug-2009	0	31-Aug-2009	10-Sep-2009	MI		10-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3021AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB326	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	UF486AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Pallor

Symptom Text: Client became lightheaded, pale and lost consciousness for 30-60 seconds while sitting on the examination table. Client was layed flat for approx 5 minutes, juice was then given and client was told to wait an additional 10 minutes in the waiting room.

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **356078-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Jul-2009	30-Jul-2009	1	31-Aug-2009	10-Sep-2009	IN		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3010AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Migraine, Vision blurred

Symptom Text: MOTHER REPORTED CHILD HAD ONSET OF MIGRANE HEADACHES, LEFT ARM NUMBNESS AND SOME BLURRED VISION. ONSET OCCURRED 1-2 DAYS FOLLOWING THE MENACTRA AND GARDASIL VACCINES. MOTHER STATES THE HEADACHES HAVE CONTINUED. PLANS TO CONTACT PEDIATRICIAN FOR EVALUATION.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE NOTED

Prex Vax Illns:

Vaers Id: **356081-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jul-2009	18-Jul-2009	0	31-Aug-2009	10-Sep-2009	AZ		03-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2769AA		Left arm	Unknown	
	HEPA	UNKNOWN MANUFACTURER	AHAVB294AD	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Amnesia, Arthralgia, Back pain, Bone pain, Confusional state, Convulsion, Dizziness, Dyspnoea, Encephalopathy, Fatigue, Headache, Hypoaesthesia, Immunisation reaction, Injection site pain, Malaise, Oedema, Oedema peripheral, Rash, Speech disorder, Syncope, Tremor, Vomiting

Symptom Text: After receiving vaccine daughter c/o pain to injection site for days. c/o headache, dizziness, "stomache ache", fatigue and general malaise. Intermittent numbness to hand/ wrist, joint and bone pain. On August 18, patient woke with swelling to finger, collapsed 15 minutes later with syncopal episode and vomiting with "seizure like activity". Pt transported to ER. Patient developed swelling to hands and feet with scattered rash. Discharged with prednisone and benedryl. Continued to c/o joint pain and fatigue with dizziness. August 24, while in school, severe dizziness, tremors with "seizure like activity", memory loss. Transient numbness to extremities. Transported to another ER and currently awaiting EEG and neurology appointment. 9/9/09 PCP medical records received DOS 8/25/08 to 8/31/09. Assessment: Medication Rxn to vaccine. Syncope. Presented at ER with edema, SOB, syncope, slow speech, confused. Ref to neurologist. 10/23/09: EEG Report received for date of service 9/15/09. Assessment: Normal awake and asleep EEG for a 15 year-old 10/23/09: EEG Report received for date of service 9/15/09. Assessment: Normal awake and asleep EEG for a 15 year-old. 10/26/09 Medical records received for date 9/21/09 Neurology consultation. Presented with c/o acute encephalopathic episodes x2 one month ago and episodes of hand, foot swelling with shoot neuropathic pains in her legs and arms. Confusion, lightheadedness, syncope, joint pains, back pain, numbness in toes/hands. Pt had gardasil one month prior to episodes. Assessment: WNL except bilateral atrophy of intrinsic hand muscles.DX: no evidence of seizure will order labs.

Other Meds: Yaz, Minocycline, (albuterol, advair, flonase precscribed but not being used at time of reaction)

Lab Data: CT scan, EKG, lumbar puncture, chest xray, CBC, CMP, sed rate, drug screen, UA. 10/23/09: EEG Report received for date of service 9/15/09. Assessment: Normal awake and asleep EEG for a 15 year-old. 10/26/09 Medical records received fo

History: asthma, acne. 9/9/09 PCP medical records received DOS 8/25/08 to 8/31/09. Asthma, allergies. Chronic folliculitis.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356083-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Aug-2009	27-Aug-2009	1	31-Aug-2009	10-Sep-2009	WI		10-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2768BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0381X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Chills, Dizziness, Headache, Nausea, Pyrexia

Symptom Text: N, stomach, dizzy, HA, backache, chills fever 102 degrees, Pt. just started monthly menstruation. Water, ice one head, ibuprofen.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **356102-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Aug-2009	21-Aug-2009	4	31-Aug-2009	10-Sep-2009	NC		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	00874	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Chills, Fatigue, Headache, Nausea

Symptom Text: Per pts. mother, pt. started experiencing extreme fatigue/weakness and some nausea in morning on 08/21/2009. Pt. was taken to PCP and Hgb check was done as pt. also started menses on 08/21/2009. Pt. felt fine all weekend and then on 8/25/09 started with headache, chills, nausea, and weakness, and was again taken to PCP and was at this time tested for influenza. Per mom, PCP is unsure of course of symptoms.

Other Meds: None

Lab Data: Hemoglobin performed on 8/21/09 - normal result per pts. mom. Influenza test - result pending.

History: Allergic to sulfa, KEFLEX, DURICEF

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356108-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	25-Aug-2009	25-Aug-2009	0	31-Aug-2009	10-Sep-2009	OH		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	06724=Y	2	Left leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Patient called our office 4 hours after receiving vaccine with c/o severe headache.

Other Meds: ORTHO TRI CYCLEN 1 tab daily

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356109-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Aug-2009	11-Aug-2009	0	31-Aug-2009	10-Sep-2009	TX		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2992AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0672Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Hypotension, Syncope, Tremor, Unresponsive to stimuli

Symptom Text: Jerking, shaking, "locked up" (2 minutes) unresponsive, hypotension. 911 called ER Dx: Syncope vasovagal.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Aug-2009	24-Aug-2009	0	31-Aug-2009	10-Sep-2009	OR		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y		Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB312AA		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0864Y		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hot flush, Nausea, Paraesthesia, Vision blurred

Symptom Text: Pt had HPV, Hep A, & Verasella. Symptoms were dizzyness, nausea, hot flash, blurry eyes & tingling ears, pt layed down for 15 min w/ ice pack.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356133-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Aug-2009	10-Aug-2009	0	31-Aug-2009	10-Sep-2009	NC		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Heart rate decreased

Symptom Text: After administration of GARDASIL vaccine patient felt like she was going to pass out. Her blood pressure dropped to 90/52 and pulse dropped to 48. Layed patient down, given a drink of soda. Rechecked patient after 10 minutes and she felt better. Blood pressure rechecked and returned to normal. Patient released.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 356183-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Apr-2007	28-Apr-2007	5	01-Sep-2009	04-Sep-2009	WA		22-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1490F	1	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U2223AA	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0188U	0	Left arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B012AA	0	Right arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anaemia, Anovulatory cycle, Blood pressure orthostatic, Menorrhagia, Thrombosis, Transfusion, Uterine dilation and curettage, Vaginal haemorrhage

Symptom Text: Presented to clinic 4/30/07 with 2d menorrhagia. Orthostatic with HCT 28.5. Admitted to hospital. Required D&C to stop bleeding, IV estrogen didn't work. D/C from hosp. 5/4/07. Transfusion x 2. Received Microgestin until 2/08. 9/18/09 Received hospital d/c summary of 4/30-5/4/2007. FINAL DX: menorrhagia; anemia; anovulation Records reveal patient experienced 11 days of menstrual bleeding with heavy blood loss & clots. Tx w/ oral & IV hormones. D&C was done 5/3/07. Transfused with PRBCs & tx w/oral iron. Improved & d/c to home. 10/20/2009 received ICD-9 codes: 625.3, 695.9, 285.1 and 259.1.

Other Meds:

Lab Data: H/H as above. 9/18/09 Hospital discharge summary received w/LABS: Pelvic US abnormal. Hgb 6.2(L). Initial von Willebrand's WNL. Coags WNL.

History: Precocious Puberty

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356189-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Jul-2009	31-Jul-2009	0	01-Sep-2009	02-Sep-2009	FR	WAES0908USA04277	02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Anorexia, Pyrexia, Weight decreased

Symptom Text: Information has been received from a pharmacist concerning a 12 year old female who on 31-JUL-2009 was vaccinated intramuscularly with the first dose of GARDASIL (lot# and site of administration not reported). On 31-JUL-2009, one hour after the administration, the patient experienced persistent dull abdominal pain. The patient was in so much pain, she had to be hospitalized on one occasion. Appendicitis, constipation and any possible gynaecological conditions were ruled out. The patient was febrile (at 102 Fahrenheit) which persisted for weeks. As a consequence to the abdominal pain, the patient was not eating and lost considerable weight. At the time of this report, the patient's outcome was unknown. The pharmacist did not know if the symptoms were related to the vaccine. Additional information has been requested.

Other Meds: Unknown

Lab Data: body temp, 102 Fahrenheit

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 356192-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	02-Dec-2008	02-Dec-2008	0	01-Sep-2009	02-Sep-2009	CA	WAES0908USA04714	02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall, Headache, Injection site pain, Insomnia, Syncope

Symptom Text: Information has been received from a physician concerning a 19 year old female patient who at the time of vaccination was with fever and congestion, on 02-Dec-2008 was vaccinated with 0.5ml of the "first and only dose" of GARDASIL (lot not reported) intramuscularly. There was no concomitant medication. On the same day of vaccination, 02-Dec-2008, the patient fainted, fell over, and had seizures after receiving her GARDASIL. The patient recovered at the office. She also experienced muscle soreness at the injection site, sleeplessness, and headaches after the vaccination from which she also recovered. Upon internal review seizures were considered to be other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness: Fever; Respiratory tract congestion

Prex Vax Illns:

Vaers Id: **356193-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	02-Aug-2008	02-Aug-2008	0	01-Sep-2009	02-Sep-2009	FR	WAES0908USA04367	02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Ataxia, Central nervous system lesion, Cerebellar syndrome, Dysarthria, Saccadic eye movement

Symptom Text: Information was obtained on request by the company from the agency via a public case details form concerning a 25 year old female who on 02-AUG-2008 was vaccinated with a dose of GARDASIL. On 02-AUG-2008, the patient experienced severe gait ataxia, moderate dysarthria, ocular dysmetria, slowed saccades, and marked dysmetria and dysdiadochokinesia of the limbs, right more than left onset over 2 weeks in September 2008. The findings were consistent with cerebellar outflow tract lesion. No changes on MRI or CSF studies to indicate multiple sclerosis. No clear response to IV METHYLPREDNISOLONE. The symptoms were improving gradually but had significant ongoing disability. The agency considered that the adverse experiences were possibly related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, no changes on MRI study to indicate multiple sclerosis; cerebrospinal fluid analysis, no changes on CSF study to indicate multiple sclerosis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 356195-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-Oct-2008	23-Oct-2008	2	01-Sep-2009	02-Sep-2009	FR	WAES0908USA04336	02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Convulsion, Encephalitis, Eye pain, Headache, Muscle spasms, Papillitis, Postictal paralysis

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail concerning a 24 year old female who on 17-JUL-2007, 04-SEP-2007 and 21-OCT-2008 was vaccinated with three doses of GARDASIL (lot# not reported) respectively. On 23-OCT-2008 the patient experienced acute disseminated encephalomyelitis and was hospitalized. It was reported that in October 2008, the patient developed pain in the right eye and subsequently developed severe bilateral papillitis. In January 2009, the patient developed headache and in early February 2009 developed tonic spasms of the left hand. Following this the patient had a generalized seizure with prolonged left-sided Todd's paresis. Laboratory evaluations of the CSF (cerebral spinal fluid) revealed white blood cell count 89, polymorphs 37% and lymphocytes count 63%. The CSF culture showed a negative result. MRI (magnetic resonance imaging) showed a signal change in right middle cerebellar peduncle and change of right hemisphere meningitis. EEG (electroencephalography) showed slowing over right hemisphere. MRI and EEG were in supporting document. In conclusion a very curious presentation of bilateral papillitis followed by a meningoencephalitis, which was not typical of MS (multiple sclerosis) or Devic's Neuromyelitis Optica. Working diagnosis was "steroid-sensitive acute disseminated encephalomyelitis (ADEM)". The patient was treated with IV methylprednisolone and then reducing course of oral steroids for her papillitis. Other symptoms were treated with further IV steroids and reducing course of oral steroids. The patient's acute disseminated encephalomyelitis persisted. The agency considered that acute disseminated encephalomyelitis was possibly related to therapy with GARDASIL. The original reporting source was not reported. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, CSF polymorphs 37%; magnetic resonance imaging, signal change in right middle cerebellar peduncle and change of right hemisphere meningitis; electroencephalography, slowing over right hemisphere; CSF lymphocyte c

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 356196-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Oct-2006	15-Dec-2008	783	01-Sep-2009	02-Sep-2009	FR	WAES0908USA04316	02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0241X		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Balance disorder, Dysarthria, Fatigue, Gait disturbance, Headache, Insomnia, Tremor

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail concerning a 16 year old female who on 24-OCT-2006 was vaccinated with GARDASIL (lot# 660614/0241X, batch # K2852). On 15-DEC-2008 the patient experienced tremor, balance disorder, dysarthria, fatigue, gait disturbance, headache and insomnia. It was reported that the patient experienced hand tremor, loss of balance, slurred speech, tiredness, headache, difficulty sleeping, not walking (short distances with a stick) and not attending school. The events required a specialist consultation - the patient saw a neurologist and was treated with ENDEP, INDERAL and EPILIM. Investigations were ongoing and inconclusive (demyelinating disease, migraine associated dysfunction). The patient has ceased medication as they made her too tired and unsteady. Laboratory evaluations revealed that: on 22-JAN-2009, antinuclear factors did not detect ANA (antinuclear antibodies). On 02-FEB-2009, magnetic resonance imaging showed apparent increased T2 signal in mid-medullary region anterolaterally on the right; radiologist concluded almost certainly artifact; otherwise normal intracranial appearance. On 02-FEB-2009, the patient had normal copper levels, ceruloplasmin, Vitamin E and celiac serology. The patient's symptoms persisted. The agency considered that tremor, balance disorder, dysarthria, fatigue, gait disturbance, headache and insomnia were disabling and possibly related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 02Feb09, apparent increased T2 signal in mid-medullary region anterolaterally on the right; magnetic resonance imaging, 02Feb09, radiologist concluded almost certainly artefact. Otherwise normal intracranial appe

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **356197-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Aug-2009	26-Aug-2009	0	01-Sep-2009	11-Sep-2009	MT		23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB326AA	2	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0381X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Pt. given Hep A VFC, instead of Hep B, VFC. She had already received 2 Hep A 's.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356199-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	09-Apr-2009	09-Apr-2009	0	01-Sep-2009	02-Sep-2009	FR	WAES0908USA04331	09-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	DE173		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1208U		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Nausea, Nystagmus

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail concerning a 25 year old female who on 09-APR-2009 was vaccinated with GARDASIL (lot# 1208U, batch# NH30330). Other suspect therapy included VAXIGRIP (lot# DE173). On 09-APR-2009 the patient experienced nausea, dizziness and nystagmus and was hospitalized. It was reported that one hour after vaccination, the patient felt faint and nauseated. Nystagmus developed soon after. The patient was treated with STEMETIL, ondansetron and IV fluids. Subsequently, the patient recovered from nausea, dizziness and nystagmus. The agency considered that nausea, dizziness and nystagmus were possibly related to therapy with GARDASIL and VAXIGRIP. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356201-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Jul-2009	07-Jul-2009	0	01-Sep-2009	11-Sep-2009	HI		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2846AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1674X	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1392X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Fever to 102, night of GARDASIL #2, Varicella #2, and MENACTRA - reduced with TYLENOL, no other symptoms.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356202-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Apr-2009	15-Apr-2009	0	01-Sep-2009	02-Sep-2009	FR	WAES0908USA04340	02-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0886X		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Grand mal convulsion

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail concerning a 15 year old female who on 15-APR-2009 was vaccinated IM with GARDASIL (lot# 661844/0886X, batch# K3755). On 15-APR-2009, 20 seconds after injection, the patient experienced grand mal convulsion (lasted 30 seconds). It was reported that the patient was lying down, as inclined to faint when she experienced the grand mal convulsion. The patient was observed till ambulance arrived then she was hospitalized. Subsequently (on 15-APR-2009), the patient recovered from grand mal convulsion. The agency considered that grand mal convulsion was possibly related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **356203-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Jul-2009	07-Jul-2009	0	01-Sep-2009	11-Sep-2009	HI		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1392X	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2846AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1674X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Fever to 102, night of GARDASIL and 2 Varicella 2 MENACTRA., resolved with Tylenol, no other symptoms.

Other Meds: None

Lab Data: None

History: No

Prex Illness: None

Prex Vax Illns:

Vaers Id: 356210-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Aug-2008	01-Oct-2008	45	01-Sep-2009	11-Sep-2009	--		31-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Autoimmune disorder, Colitis, Colitis ulcerative, Haematochezia

Symptom Text: Female vaccinated with GARDASIL. Shortly after she developed Colitis, inflammatory bowel disease, an autoimmune disease. 12/18/09 MR received for DOS 12/31/08. Chief complaint: Hematochezia. Pt c/o bright red stool in the stool. Pt reported 3 bowel movements per day. System review negative. Rectal exam revealed no hemorrhoids. Tx: imiquimod topical. MR for DOS 07/28/09. Pt reported DX of Colitis given by the GI specialist. Pt had reoccurrence of blood in stool. Pt treated with Omeprazole, prednisone, imiquimod topical. MR for DOS 08/06/09. Pt started Asacol per GI specialist. MR for DOS 10/26/09. DX: Ulcerative colitis. Physician discussed with Pt possible relation of HPV vaccine to this event, but stated that likely no causal link will ever be established. Pt counseled about the risk of cervical cancer and importance of routine screening. Tx: Mesalamine.

Other Meds:

Lab Data: DX studies on 01/05/09: RBC: 4.95 (H), Hct: 42.5% (H), Occult blood 1st in stool: positive.

History: No preexisting medical condition. PMH: plantar warts, URI, seborrheic dermatitis, irritable bowel syndrome, warts; Allergies: NKDA

Prex Illness:

Prex Vax Illns:

Vaers Id: **356212-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Aug-2009	17-Aug-2009	0	01-Sep-2009	11-Sep-2009	WV	WV0907	11-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0067X	0	Left arm	Subcutaneously	
VARCEL	MERCK & CO. INC.	0194Y	1	Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334CA	0	Left arm	Intramuscular	
HEP	MERCK & CO. INC.	0874Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Syncope

Symptom Text: Fainting/feeling hot. Placed patient on floor, resp, pulse were normal limits. Pt recovered quickly, keep lying down for 15 minutes. No adverse affects noted.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356226-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Aug-2009	18-Aug-2009	0	01-Sep-2009	11-Sep-2009	MA		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	43016AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Dizziness, Fatigue, Heart rate increased, Nausea, Presyncope

Symptom Text: Near syncope - some chest pain & dizziness nausea. 2nd episode 19th/8/09 (same SX). 9/3/09-records recived-date of service 8/25/09-2 episodes of basically near syncope, chest pain and nausea associated with it-dizziness and lightheadedness. First occurred on 8/19/09. Heart beat felt rapid. Second episode on same day. General sense of fatigue which is longstanding.C/O back pain in office day vaccines administered.

Other Meds:

Lab Data:

History: No 9/3/09-records received- Mom has history of panic attacks.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356236-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jul-2009	22-Jul-2009	6	01-Sep-2009	11-Sep-2009	MS		11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pyrexia

Symptom Text: Severe headache with fever 100 degrees F on 7/23/09.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356241-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Jul-2009	01-Aug-2009	19	01-Sep-2009	04-Sep-2009	IL		07-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Fall, Syncope

Symptom Text: Patient received HPV #3 on 07/13/09. No immediate adverse events noted. Patient presented to ER on 08/01/09 with syncope and again on 08/24/09 with possible seizures. 9/3/09-records received for follow-up visit 3/23/09-school physical-no complaints-Rash on face. Seb. Dermatitis. ED visit 8/1/09-and 8/24/09 for syncopal episode after getting out of hottub, flushing, lightheadedness and palpitations. Admitted for 3 days and to follow up with neurologist. Family HX of seizure disorder. 10/5/09 Hospital records and DC summary received, service dates 8/1/09 to 8/4/09. Assessment: Status post fall with questionable loss on consciousness. Patient found by family face down after falling in bathtub with almost 1 foot of water. Some amnesia and questionable loss of consciousness.. No apparent injuries or acute injuries. No deformities of extremities.

Other Meds: None

Lab Data: LABS and DIAGNOSTICS: CT - Negative. X-rays of C-spine, chest, abdomen, pelvis - Negative. CHEM - Glucose 134 mg/dL (H) CO2 21 mEq/L (L) BUN 5 mg/dL (L). Urine drug screen (-). Urinalysis - Leuk Est (+), Protein trace, Blood trace, ketones

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 356265-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Aug-2009	22-Aug-2009	0	01-Sep-2009	04-Sep-2009	FL		11-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	02164	1	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB706AA	1	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3158AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3012AA	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drooling, Eyelid function disorder, Facial nerve disorder, Facial palsy, Facial paresis, Hypoaesthesia facial, Inflammation, Throat lesion

Symptom Text: Bell's palsy (unilateral). 9/2/09 Consultant record received DOS 8/31/09. Assessment: Bell's Palsy. Patient presents with sudden onset (L) facial palsy / weakness. Feeling of weakness on (R) side. 9/17/09 Hospital records received DOS 8/31/09 to 9/1/09. Assessment: Bell's Palsy. Patient visiting from Mexico, presents with 2 day history of right facial numbness. Could not close left eye, drooling from left side of mouth. Facial numbness. Peripheral facial nerve palsy, asymmetry of forehead wrinkles, mouth asymmetry. White exudates left peritonsillar recess. Patient immproved.

Other Meds: No

Lab Data: MRI brain normal. 9/2/09 Consultant record received DOS 8/31/09. 9/17/09 Hospital records received DOS 8/31/09 to 9/1/09. LABS and DIAGNOSTICS Flu (-). LABS and DIAGNOSTICS: MRI Brain - Normal. Influenza A/B antigen (-) Throat Culture - No

History: No

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356281-1** **Related reports:** 356281-2; 356281-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Aug-2009	26-Aug-2009	0	01-Sep-2009	11-Sep-2009	CO		06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB296BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Balance disorder, Dizziness, Fall, Gait disturbance, Haematemesis, Haemorrhage intracranial, Head injury, Headache, Loss of consciousness, Pain in extremity, Skull fracture, Subdural haematoma, Syncope, Vomiting

Symptom Text: Patient administered Hep A and HPV vaccine. Sat in clinic room 10-15 minutes. Stated felt fine, color good. released to check out. stood 1-2 minutes and fell, possibly fainting, hitting head 9/22/09 ED and medical records received DOS 4/20/09 to 9/03/09. Assessment: Skull fracture and intracranial hemorrhage secondary to vasovagal syncope. Patient presents with headache and vomiting after syncope and a fall. Had felt light headed and lost consciousness, struck back of head on ground. Occipital skull fracture. Anterior intraparenchymal bleed and small subdural hemorrhage, occipital fracture, hematemesis. Pain left buttock and posterior left leg. Off balance gait. 10/2/09 Received ICD9 codes: 80121; 7802.

Other Meds:

Lab Data: 9/22/09 Medical records received w/LABS: CT Head - Abnormal. CBC - WBC 14.8 3/uL (H) RBC 4.05 6/uL (L) Hematocrit 34.1% (L) Seg Neut 91.5% (H) Lymph 4.6% (L) Seg Neut ABS 13.5 (H) Lymph ABS 0.7 (L)

History: none known 9/22/09 Medical records received w/PMH: Left knee discomfort and left knee chondromalacia patella.

Prex Illness: None known

Prex Vax Illns:

Vaers Id: **356281-2 (S)** **Related reports:** 356281-1; 356281-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Aug-2009	26-Aug-2009	0	11-Sep-2009	21-Sep-2009	CO		30-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB296BA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	1497X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Dizziness, Fall, Gait disturbance, Haematemesis, Head injury, Loss of consciousness, Musculoskeletal pain, Pain in extremity, Skull fracture, Subarachnoid haemorrhage, Syncope

Symptom Text: Pt is a 16 year old female who suffered an injury to occiput due to loss of conciousness after receiving a gardasil and hep A vaccine at her the public clinic. Pt presented to ER vomiting copious amount and with moderate amounts of bright red blood. CT revealed a subarachnoid hemorrhage. Pt was observed overnight at the Hospital and had now acute events. Pts symptoms have now resolved w/ the exception of some musculoskeletal pain. 9/22/09 ED and medical records received DOS 4/20/09 to 9/03/09. Assessment: Skull fracture and intracranial hemorrhage secondary to vasovagal syncope. Patient presents with headache and vomiting after syncope and a fall. Had felt light headed and lost consciousness, struck back of head on ground. Occipital skull fracture. Anterior intraparenchymal bleed and small subdural hemorrhage, occipital fracture, hematemesis. Pain left buttock and posterior left leg. Off balance gait.

Other Meds: none

Lab Data: CT Head shows subarachnoid hemorrhage and occipital skull fracture. 9/22/09 ED and medical records received DOS 4/20/09 to 9/03/09. CT Head - Abnormal. CBC - WBC 14.8 3/uL (H) RBC 4.05 6/uL (L) Hematocrit 34.1% (L) Seg Neut 91.5% (H) Lymp

History: none. 9/22/09 ED and medical records received DOS 4/20/09 to 9/03/09. Left knee discomfort and left knee chondromalacia patella.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **356281-3 (S)** **Related reports:** 356281-1; 356281-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Aug-2009	26-Aug-2009	0	07-Dec-2009	08-Dec-2009	--	WAES0911USA01066	26-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB296BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Arthralgia, Balance disorder, Cerebral haemorrhage, Computerised tomogram abnormal, Dizziness, Fall, Gait disturbance, Haematemesis, Haemorrhage intracranial, Head injury, Headache, Loss of consciousness, Musculoskeletal pain, Pain in extremity, Skull fractured base, Subarachnoid haemorrhage, Syncope, Vomiting

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 16 year old female with left knee discomfort and left knee chondromalacia patellae on 26-AUG-2009 was vaccinated with the first dose of GARDASIL IM into the left arm (therapy dose unknown) (Lot # 662229/1497X). Concomitant therapy included the first dose of HAVRIX IM into the left arm (therapy dose unknown) (Lot # AHAVB296BA) and DTaP (unspecified) (therapy dose, site and route unknown) (manufacturer unknown). The patient sat in clinic room 10-15 minutes after administration those vaccine. The patient stated felt fine, color good and was released to check out. The patient stood 1-2 minutes and fell, possibly fainting and hitting head. The patient presented to the emergency room vomiting copious amount and with moderate amounts of bright red blood. CT revealed a subarachnoid hemorrhage and occipital skull fracture. The patient was observed overnight at the hospital and had now acute events. The patient's symptoms had now resolved except some musculoskeletal pain. On 22-SEP-2009 emergency department and medical records were received concerning the patient's status of 20-APR-2009 to 03-SEP-2009. Assessment showed skull fracture and intracranial hemorrhage secondary to vasovagal syncope. WBC 14.8 3/Ul (H), RBC 4.05 6/Ul (L), Hematocrit 34.1% (L), Seg Neut 91.5% (H) Lymph 4.6% (L), Seg Neut ABS 13.5 (H), Lymph ABS 0.7 (L). The patient presented with headache and vomiting after syncope and a fall. The patient felt light headed and lost consciousness, struck back of head on ground, occipital skull fracture, anterior intraparenchymal bleed and small subdural hemorrhage, occipital fracture, hematemeisis, pain left buttock and posterior left leg, off balance gait. Upon internal review, haemorrhage intracranial was considered to be an other important medical event. The original reporting source was not provided. The VAERS ID # is 356281. A standard lot check investigation had been finalized.

Other Meds:

Lab Data: head computed axial, subdural hemorrhage, occipital skull fracture; diagnostic laboratory, Seg Neut ABS 13.5 (H); diagnostic laboratory, Seg Lymph ABS 0.7 (L); WBC count, 14.8 3/uL (H); red blood cell count, 4.05 6/uL (L); hematocrit, 34.1%

History:

Prex Illness: Low extremities discomfort; Chondromalacia patellae

Prex Vax Illns:

Vaers Id: **356285-1 (S)** **Related reports:** 356285-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Aug-2009	28-Aug-2009	15	01-Sep-2009	04-Sep-2009	LA		15-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthma, Chest pain, Convulsion, Cough, Crying, Dizziness, Dyspnoea, Facial palsy, Headache, Hyperventilation, Hypoaesthesia, Hypokalaemia, Muscle spasms, Musculoskeletal stiffness, Myalgia, Nausea, Pain in extremity, Palpitations, Rash, Speech disorder, Tachypnoea, Vaccination complication, Vision blurred

Symptom Text: Stiffening and aching muscles, chest pain, racing heart, aching leg (both), aching arm (both), shortness of breath, dizziness, nausea, rash, seizure-like activity (bottom of right lip drooped downward and she could not speak intelligibly), her fingers were opened straight out with the tips pointed toward the bone), headache, and blurry vision. 10/14/09 ED and Hospital records received service dates 8/28/09 to 8/31/09. Assessment: Asthma, acute exacerbation. Side effects from Gardasil. Hypokalemia. Patient is short of breath and presents with tachypnea. Cough. Crying. Hyperventilation. Improves after breathing into paper sack. Presents again with trouble breathing and shortness of breath. Cramping and numbness of extremities. ICD-9 codes: 995.20 Unspecified adverse effect of unspecified drug, medicinal and biological substance, 276.8 Hypokalemia, E949.6 Adverse effects of other and unspecified viral and rickettsial vaccines.

Other Meds: None

Lab Data: EKG (results were normal), checked oxygen level (results were 100%), blood levels were checked (potassium was slightly low), kidneys and liver were checked (these were normal). 10/14/09 ED and Hospital records received service dates 8/28/0

History: Sinusitis and. 10/14/09 ED and Hospital records received service dates 8/28/09 to 8/31/09. Asthma. Tonsillectomy.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356285-2 (S)** **Related reports:** 356285-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Aug-2009	28-Aug-2009	15	14-Sep-2009	21-Sep-2009	LA	LA090901	21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Dyspnoea, Muscle tightness, Tachycardia, Vision blurred

Symptom Text: SOB - tachycardia, muscles drawing, dizziness, blurred vision. Kept in hosp 1 day - another episode same s/sx on Monday 8-31-09.

Other Meds: Singulair 10 mg once daily; Proventil inhaler

Lab Data: EKG (Normal);O2 sats - 100%; CMP - Potassium slight increased

History: NKDA; Asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356304-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Aug-2009	26-Aug-2009	0	02-Sep-2009	03-Sep-2009	OK	WAES0908USA04708	28-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC528046AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0312Y	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2815AA		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	0498Y		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Confusional state, Convulsion, Dyskinesia, Fatigue, Gaze palsy, Musculoskeletal stiffness, Staring

Symptom Text: Information has been received from a physician and an office manager concerning a 12 year old female patient with amoxicillin allergy (AMOXILIN) who on 26-AUG-2009 was vaccinated with the first 0.5 ml of a dose of GARDASIL, concomitantly with a dose of BOOSTRIX (Lot: AC528046AA), a dose of VARIVAX (Lot: 664232/0498Y) and a dose of MENACTRA (Lot: U2815AA). The patient stated that after the vaccinations she felt tired. She went home and had a seizure. The patient went to Emergency room and had computed axial tomography (CAT) done (results not reported). The patient was not hospitalized. The patient's mother called on 27-AUG-2009 at the Physician's office and stated that her daughter was doing better. The physician also stated that he did not consider the events to be Life threatening or to have caused the patient significant Disability or Incapacity. Upon internal review seizure was considered as other important medical event. Additional information has been requested. 9/21/09 ER records received for DOS 8/26/09 with dx: possible seizure by hx with normal exam in ER. Pt presented after episode of staring, becoming stiff, shaking and jerking, eyes rolling back in head and lack of memory of event. Confused after.

Other Meds: Unknown

Lab Data: computed axial, 08/26/09 Labs and diagnostics: CT brain WNL. CBC/CMP WNL. drug screen (-). EEG abnormal. EKG NSR. BS 104.

History: PMH: allergy to Amoxicillin/

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: 356305-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Apr-2008	01-May-2009	395	02-Sep-2009	03-Sep-2009	FR	WAES0908USA04840	03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	PPV	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blood product transfusion, Inappropriate schedule of drug administration, Lymphopenia, Thrombocytopenia, Vaccine positive rechallenge

Symptom Text: Case of misuse received from a Health Authority (HA reference number BX20090477 and BX0900533). This case is linked to serious case WAES 0908USA01100 (same vaccine, same patient, different events). A 15 year old female with a history of HIV positive since her birth (mother to child contamination) had received the first dose of GARDASIL (batch number, lot number and route not reported) in April 2008 and a dose of PNEUMOVAX (batch number, lot number and route not reported) in April 2008. After vaccination, her viral load was very slightly positive at 68 copies, but she experienced a marked decrease of CD4 T cells on a background of lymphopenia at a 0.797 (G/L (see linked case). She received the second dose of GARDASIL (batch number , lot number and route not reported) in May 2009, after CD4 lymphocytes had increased (>0.700 G/L). Consequently, it was an inappropriate schedule of vaccination as she received the second dose on May 2009, i.e. more that one year. One month after the second dose, she developed thrombocytopenia and decreased CD4 Cells. She was hospitalized during one night to received intravenous injection of immunoglobulins. The patient was found to have platelet count at 6 on 24-JUN-2009, at 9 25-JUN-2009, at 97 on 03-JUL-2009 (normal range: 140-450 g/L). As reported, in April 2006, her CD4 T cells (normal range: 0.7-1.1 G/L) were at 0.199. On 24-JUN-2009, her CD4 T cells were at 0.478 and her viral load at 2964 copies/mL. To be noted that the HA coded second dose of GARDASIL as suspect, thrombocytopenia and lymphocytes CD4 decreased as adverse events, and positive rechallenge. The imputability was assessed as doubtful (C2S1) by the HA. The Health Authority specified that the imputability "doubtful" (C2S1) was assessed for thrombocytopenia. At the time of reporting, the patient had not recovered. Other business partner number included: E2009-08236. Additional information has been requested.

Other Meds: Unknown

Lab Data: blood CD4 count, ??Apr06, 0.199 G/L; blood CD4 count, ??Apr08, 0.797 G/L; plasma HIV RNA quantification, ??Apr08, 68 copies/mL; blood CD4 count, ??May09, >0.700 G/L; blood CD4 count, 24Jun09, 0.478 G/L; plasma HIV RNA quantification, 24Jun0

History:

Prex Illness: HIV infection

Prex Vax Illns:

Vaers Id: **356306-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Mar-2009	01-Apr-2009	8	02-Sep-2009	03-Sep-2009	FR	WAES0908USA04751	03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1114U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune thyroiditis

Symptom Text: Information has been received on 26-AUG-2009 from a pediatrician concerning a 17 year old female patient with no medical history reported who on 11-SEP-2008 was vaccinated intramuscularly with the first dose of GARDASIL (batch# NH15190, lot# 1114U) into the left upper arm. On 24-MAR-2009 the patient was vaccinated intramuscularly with the second dose of GARDASIL (batch# NH10940, lot# 1114U) into the left upper arm. In April 2009, the patient experienced hashimoto's-thyroiditis (not specified) and in July 2009 the diagnosis was established. Laboratory values showed increased thyroid hormones and antibodies. fT3 (free triiodothyronine) was 26.8pmol/L; fT4 (free thyroxine) was 40.2/pmol/L; Thyreoperoxidase-Antibodies (anti-TPO) was 231 U/ml. At the time of this report the patient just suffered from hyperthyroitic situation. The physician prognosed a life-long need for medication and therefore a remaining damage. He assessed the relation between the vaccinations and the adverse event as possible. File is closed. Hashimoto's-thyroiditis was considered to be an other medically important condition. Other business partner numbers included: E2009-08219. No further information is available.

Other Meds: Unknown

Lab Data: free serum thyroxine, 40.2 pmol/L; serum antithyroid peroxidase antibody, 231 U/ml; free serum triiodothyronine test, 26.8 pmol/L

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356307-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Jul-2009	15-Aug-2009	30	02-Sep-2009	03-Sep-2009	FR	WAES0908USA04561	03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1695U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Burning sensation, Paraesthesia

Symptom Text: Information has been received from a gynaecologist via an agency as part of business agreement concerning a 15 year old female patient who on 16-JUL-2009 was vaccinated IM into the left upper arm with the first dose of GARDASIL (batch number NH25730, lot number 1695U). On 15-AUG-2009 the patient experienced paraesthesia with tingling and burning in all extremities. On 16-AUG-2009 the patient experienced severe lumbar back pain. The same day she was admitted to hospital (neurological department). All examinations were without pathological findings. On 19-AUG-2009 she was discharged with improved symptoms. At the time of the report the patient had not recovered. Other business partner numbers include E2009-08161.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **356308-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Aug-2007	Unknown		02-Sep-2009	03-Sep-2009	FR	WAES0908USA04557	03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cachexia, Decreased appetite, Dysphagia, Oesophageal disorder

Symptom Text: Information has been received from a general practitioner concerning a 16 year old female patient who in August or September 2007, was vaccinated with the first dose of GARDASIL (lot number, injection site and route not reported). On an unspecified date shortly prior to vaccination, the patient had also received meningococcal vaccine (unspecified) (manufacturer unknown). Shortly after the vaccination, the patient experienced dysphagia (difficulties swallowing), followed by anorexia and cachexia. She was admitted to hospital in a medical department, but also in a psychosomatic department. All exams were without pathological findings, only a "slight oesophageal tonus disorder" was diagnosed. No written hospital reports were provided yet. The reporter stated that the patient was recovered from the events (weight 43 kg, height 163 cm). In contact to the parents of the patient, the family doctor does not consider the events as side effects of the vaccines. Nevertheless, he contacted the company to inquire whether there are similar cases reported. Other business partner numbers include E2009-08151.

Other Meds: meningococcal vaccine (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 356309-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	27-May-2009	27-May-2009	0	02-Sep-2009	03-Sep-2009	FR	WAES0908USA04383	03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Asthenia, Circulatory collapse, Dizziness, Dyspnoea, Fatigue, Immediate post-injection reaction, Lethargy, Loss of consciousness, Malaise, Myalgia, Nausea, Pallor, Shock, Syncope

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail concerning a 21 year old female who on 27-MAY-2009 was vaccinated with a dose of GARDASIL intramuscularly (site not reported). Concomitant therapy included DIANE 35 ED and ZOLOFT. On 27-MAY-2009 the patient felt dizzy immediately after injection with symptoms of fainting and unaware of events as they lay her on the floor in the Doctor's surgery. The patient was unconscious for 25 minutes. Almost cardiac arrest. Nausea, shock, dizziness, shortness of breath, pallor, tiredness, lethargy and weakness, aching neck muscles for 48 hours after. Paramedics in attendance for transportation to hospital, she was given oxygen, MAXOLON and PANADOL. Circulatory collapse, asthenia, dizziness, dyspnoea, fatigue, lethargy, malaise, myalgia, nausea and pallor were considered to be immediately life-threatening. The original reporting source was not provided. No further information is available.

Other Meds: DIANE 35 ED; ZOLOFT

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **356310-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	31-Jul-2009	21-Aug-2009	21	02-Sep-2009	03-Sep-2009	FR	WAES0908KOR00028	03-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Intracranial pressure increased, Optic nerve injury, Vision blurred

Symptom Text: Information has been received from a physician concerning an 18 year old female who on approximately 31-JUL-2009 was vaccinated with the first dose of GARDASIL. Concomitant therapy included hepatitis B virus vaccine (unspecified), which was vaccinated with GARDASIL (first dose) on the same day. On 21-AUG-2009 (3 weeks after vaccination) the patient was hospitalized due to the blurred vision. After examinations, the patient was diagnosed with the intracranial hypertension and injury of optic nerve due to intracranial hypertension. The blurred vision was the symptom of injury of optic nerve. However if the patient was diagnosed with optic neuritis or not was not determined yet. The patient was treated with unspecified medication which had the lowering effect of the brain pressure, and was followed up for finding the cause. The patient had no medical history, concurrent disease and concomitant medication except hepatitis B virus vaccine. The patient's intracranial hypertension and injury of optic nerve persisted. The reporting physician reported that the causal relationship with GARDASIL was unknown so far. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **356323-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Jun-2007	22-Jul-2007	47	02-Sep-2009	08-Sep-2009	NM		02-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0089U	1	Left leg	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abnormal behaviour, Aggression, Agitation, Asthenia, Blood product transfusion, Brain injury, Cognitive disorder, Convulsion, Diabetes mellitus, Disinhibition, Ear pain, Eating disorder, Encephalitis, Heart rate increased, Hypertension, Hypoaesthesia, Impulsive behaviour, Insomnia, Lacrimation increased, Oral contraception, Otitis media, Pain, Palpitations, Panic attack, Salivary hypersecretion, Sinus tachycardia, Skin discolouration, Type 1 diabetes mellitus, Vomiting, Vulvovaginal mycotic infection

Symptom Text: Aggression, seizures, rapid heart rate, brain damage, weakness, no sleep, changing skin color & textures, pain, numbness. 9/14/09 Hospital records received DOS 3/13/08 to 4/7/08. Assessment: Seizure activity with behavioral disorder. Insulin dependent diabetes mellitus. Patient transferred from another facility. Behavioral changes including defiance and disinhibited behaviors. Palpitations and transient sinus tachycardia. Agitation, aggression. Panic attacks. IVIG administration. 9/14/09 Hospital records received DOS 3/13/08 to 7/15/08. Additional information abstracted. Assessment: Meningoencephalitis with neurocognitive disturbance and disinhibition. Vaginal yeast infection. Patient c/o of palpitations. Emesis. Impulsive, compulsive eating behaviors. Increased lacrimation and salivation. Oral contraception. ICD-9 Codes: 345.90, 323.9, 341.9, 343.0, 293.0 307.51, 345.40, 343.9, 302.70, 312.9, 294.9, 310.1 293.84, 309.81, 296.90, 780.52, 250.92, 706.1, 274.9, 626.0 112.1 V15.81, V58.67, 313.81, 345.40, 293.89, 250.01, 298.9 ```records received 01/20/2010. Clinic records for DOS 06/05/07 and 01/15/08. Assessment: Type I diabetes mellitus, Behavior problems Patient received Gardasil#2 on 06/05/07 and Gardasil#3 on 01/15/08. Clinic rec. of 01/15/08 notes mother reports patient is giving herself extra insulin and is eating things she shouldn't. ```` records received 01/19/2010. Clinic progress notes received for DOS 03/27/07-01/04/2010. Assessment: Bilateral otitis media, heart palpitations, Diabetes (out of control), behavior problems, not sleeping, vomiting, sleep disorder and uncontrolled seizures due to limbic encephalitis, hypertension. . Patient received Gardasil#1 on 03/27/07 and progress note documents good sleep habits and DM (DX in Jan 06) in good control. Clinic rec. of 07/20/07, patient c/o bad ear pain since Monday, went swimming in river in Germany. Tx: Amoxicillin. Clinic rec. of 08/20/07, patient c/o heart palpitations. Patient also felt palpitations at the end of last

Other Meds:

Lab Data: 9/14/09 Hospital records received DOS 3/13/08 to 7/15/08. LABS and DIAGNOSTICS: Thyroid Ultrasound - Normal. TSH -Normal. Thyroid Peroxides Antibodies 66.1 elevated. EEG - Abnormal. MRI Brain - Abnormal. CBC - MCV 94 (H) RDWC 14.6% (H) N

History: Type I DM; Mild cerebral palsy but was an honor student. 9/14/09 Hospital records received DOS 3/13/08 to 7/15/08. Mild spastic diplegia cerebral palsy. Insulin-dependent diabetes mellitus.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356328-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Jun-2008	10-Nov-2008	160	02-Sep-2009	22-Sep-2009	IN		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U		Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Arrhythmia, Atrioventricular block, Bradycardia, Cardiac murmur, Chest pain, Contusion, Dizziness, Fatigue, Head injury, Loss of consciousness, Menstruation irregular, Nasal congestion, Sinus arrhythmia, Sinusitis, Somnolence, Syncope, Weight decreased

Symptom Text: Bradycardia, arrythmias, heart block, syncope, chest pains. Taking 3 kinds of medicine daily. Has plenty of follow ups with cardiologists, possibly put in a pacemaker. 9/25/09 ER records reeived DOS 11/10/08 and 11/22/08. Assessment: syncopal episodes, sinusitis, sinus arrhythmia. Patient felt dizzy, passed out, hit side of head. Presents at ER awake and alert saying she feels tired. Lost 40 lbs during the past year. Irregular periods. Nose stuffy. Drowsy. Bump on side of head. Systolic murmur left sternal border. 11/2/2009 records from 6/4-6/7/2009 and ED visit 8/5/2009. Patient was seen for c/o's syncope on both occasions. Tx: telemetry, lab and echo normal, Ekg noted bradycardia. Patient discharged with Holter monitor. Dx: vasovagal syncope

Other Meds: None

Lab Data: EKG; Echocardiogram; Tilt table test; EEG; Bloodwork. LABS and DIAGNOSTICS: EKG - Abnormal, sinus bradycardia with A-V dissociation and junctional rhythm. Chest X-ray - Minimal scoliosis, otherwise normal. CT Head - Sphenoid sinusitis, oth

History: None. Caffeine beverages. PMH: none Allergies: NKDA

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356330-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	05-Aug-2009	06-Aug-2009	1	02-Sep-2009	14-Sep-2009	NC		14-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0690Y	1	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0087Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB34BA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Angioedema

Symptom Text: Angioedema 8 cm on right posterior arm. S/S started following the vaccination.

Other Meds:

Lab Data: CBC & CRP.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356334-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	18-Dec-2008	01-May-2009	134	02-Sep-2009	22-Sep-2009	LA		15-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Headache

Symptom Text: Severe hair loss. Headaches. 10/14/09 PC note servce dates 12/18/09 to 8/6/09. Patient's hair is falling out.

Other Meds: None

Lab Data: blood work 8-14-09 to check for cause of hair loss

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356357-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Aug-2009	01-Sep-2009	1	02-Sep-2009	14-Sep-2009	NV		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Pain in extremity, Pyrexia, Vomiting

Symptom Text: Sore arm evening of vaccination. Woke up 4am, vomiting, chills, fever. Lasted 12 hours and symptoms subsided. No treatment neccessary

Other Meds: Yaz

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **356373-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	31-Aug-2009	31-Aug-2009	0	02-Sep-2009	04-Sep-2009	NJ		04-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	10134	1	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Aura, Fall, Head injury, Postictal state, Syncope, Tonic clonic movements

Symptom Text: About 5 minutes after receiving Gardasil, patient syncopized with tonic-clonic movements, described an aura and had a brief post-ictal period. She was standing at the onset and fell backwards hitting her head on the floor.

Other Meds: None

Lab Data: NCHCT reportedly wnl, Chemistry and CBC wnl. EEG performed results pending and pt will receive and MRI

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356391-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Aug-2009	Unknown		02-Sep-2009	14-Sep-2009	NM		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Nausea, Vomiting

Symptom Text: Pt had nausea & vomiting after GARDASIL vaccine.

Other Meds:

Lab Data: None

History: Was already having nausea & vomiting.

Prex Illness: Nausea & vomiting

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356394-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Sep-2009	01-Sep-2009	0	02-Sep-2009	14-Sep-2009	OH		14-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood test, Syncope

Symptom Text: Pt got GARDASIL # 3 given as injection; approximately 5 mins later stood up; was walking out of room and fainted. Pt also had blood drawn as well and hadn't eaten much that day.

Other Meds: On birth control (TRI-PHASIL)

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356398-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	29-Aug-2009	01-Sep-2009	3	02-Sep-2009	14-Sep-2009	NY		14-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0110Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Malaise, Oropharyngeal pain, Pyrexia, Vomiting

Symptom Text: FEVER ONSET 9/1 at 9PM,CHILLS, THROAT PAIN, VOMITING TODAY 9/2. General Malaise.

Other Meds: NONE

Lab Data: THROAT CULTURE OBTAINED 9/2

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **356413-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Jun-2009	15-Jun-2009	0	03-Sep-2009	04-Sep-2009	FR	WAES0907USA00112	04-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Case of pregnancy follow up reported by a physician GARDASIL pregnancy registry on 23-JUN-2009. A 17 year old female patient received the third dose of GARDASIL (Batch # not reported) on 15-JUN-2009. She had just started a spontaneous pregnancy. There was no personal or familial medical history. The patient would probably carry on the pregnancy. No reaction was reported. Follow up information received through a letter form the gynecologist on 28-AUG-2009. The case was upgraded to serious based upon the following information: The patient experienced a spontaneous abortion approximately in the middle of August 2009. Other business partner numbers include E2009-05249. No further information expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **356414-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	07-Aug-2009	07-Aug-2009	0	03-Sep-2009	04-Sep-2009	CA	WAES0908USA04339	04-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	UF471AA		Unknown	Unknown	
MNQ	SANOFI PASTEUR	U2846AA		Unknown	Unknown	
HPV4	MERCK & CO. INC.	0162Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Contusion, Convulsion, Fall, Headache, Nausea, Syncope

Symptom Text: Information has been received from a physician and the medical assistant concerning a 19 year old female with no known drug allergies who "two weeks ago" on 07-AUG-2009 was vaccinated with her first dose of GARDASIL 0.5 mL, intramuscularly, Lot# 0162Y. Concomitant therapy included ADACEL Lot# UF471AA and MENACTRA U2846AA. On 07-AUG-2009, five minutes after the patient received the vaccinations, she stood up to walk to the waiting room. The patient fell to the floor, face down. The patient had syncope and seizure like activity for 5 minutes. The ambulance was called. The patient regained consciousness and was observed in the office. The patient did not go to the hospital at that time. The patient went home accompanied by her mother and aunt. On 08-AUG-2009, the patient went to the Emergency Room and complained of headache and nausea. The patient had a CT scan with normal results. The patient had bruises of the right elbow and right hip. The patient was not admitted to the hospital. The patient had recovered. The patient had a follow-up visit with the physician on 14-AUG-2009. Syncope and seizure like activity were considered to be disabling. This is one of several reports from the same source. Additional information has been requested.

Other Meds:

Lab Data: computed axial, 08/08/09, Normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 356415-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	30-Mar-2009	30-Mar-2009	0	03-Sep-2009	04-Sep-2009	FR	WAES0908USA04418	04-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest discomfort, Dyspnoea, Flushing, Hypersensitivity, Inappropriate schedule of drug administration, Pruritus, Tremor

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail concerning a 28 year old female who on 30-MAR-2009 was vaccinated with a 120 mcg dose of GARDASIL intramuscularly. Concomitant therapy included CARDIPRIN, EPILIM, MOTILIUM, NEXIUM, NORVASC and "Notan". On 30-MAR-2009 the patient experienced hypersensitivity, chest discomfort, dyspnoea, flushing, pruritus and tremor and was hospitalized. The reaction occurred within 5 minutes of GARDASIL administration. The patient was treated with ranitidine 50 mg IV, atenolol 25 mg, dexamethasone (manufacturer unknown) 4 mg IV, promethazine and aspirin 100 mg. At the time of the report, the patient had recovered. The agency felt that hypersensitivity, chest discomfort, dyspnoea, flushing, pruritus and tremor were probably related to vaccination with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: CARDIPRIN; EPILIM; MOTILIUM; NEXIUM; NORVASC

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356416-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2008	23-Aug-2008	11	03-Sep-2009	04-Sep-2009	FR	WAES0908USA04938	04-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1172U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from an internist concerning a 17 year old female who on 08-FEB-2008 was vaccinated with a first dose of GARDASIL (lot# 1539F; batch# NF42170) IM, into her upper arm and a second dose of GARDASIL (lot# 1172U; batch# NH13130) IM, into the upper arm on 12-AUG-2008. On 23-AUG-2008 the patient experienced a first attack of encephalomyelitis disseminata (multiple sclerosis). Initially suspicion of parainfectious encephalomyelitis was established. But the diagnosis of multiple sclerosis was supported by a second attack on 21-JUL-2009. The reporter stated a "persisting damage" and assessed the relation between the adverse event and the vaccines as possible. Multiple sclerosis was considered an other important medical event. Other business partner numbers include: E2009-08249. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 356417-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	18-Oct-2007	18-Oct-2007	0	03-Sep-2009	04-Sep-2009	VA	WAES0908USA04943	16-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Adnexa uteri pain, Condition aggravated, Dizziness, Injection site pain, Injection site swelling, Nausea, Ovarian cyst ruptured, Pain, Vaccine positive rechallenge

Symptom Text: Information has been received from an approximately 25 year old female patient with "cysts in the ovaries that were not a problem", papilloma viral infection and an allergy to benzyl peroxide and a history of caesarean section (2002) who in 2008 was vaccinated with GARDASIL. The consumer already had HPV prior to vaccination with GARDASIL. Concomitant therapy included DEPO-PROVERA. The patient reported that she experienced dizziness after each dose of GARDASIL. All 3 doses were given over a 6 month period. The physician assistant recommended GARDASIL because "it would be helpful for her current HPV infection". The dizziness lasted for a couple of weeks after each vaccination. There was swelling at the site of injection after each dose and the site was pretty painful for 2 or 3 days. There was an occasional nausea within 1 week after each dose which seemed to coincide with the dizziness. The dizziness seemed to cause the nausea. The patient also had increased pain with cysts in the ovaries that had gotten worse since she received all 3 doses. ON approximately 28-JUL-2009 one of the cysts that was 2 inches in size ruptured and the patient was hospitalized. The patient still has day to day pain from the cysts. The patient did not have dizziness or nausea that stopped a few weeks after the 3rd dose of GARDASIL. At the time of the report the patient was not recovered from the other adverse events. The patient sought medical attention at office visit. On an unknown date a blood test was performed and it was normal, also a biopsy of cervix prior to vaccinations was performed (results not provided). Additional information has been requested. 9/14/09 PCP medical records received DOS 9/7/07 to 10/18/07. Patient complains of ovarian pain and cyst.

Other Meds: DEPO-PROVERA

Lab Data: diagnostic laboratory, Blood test Normal. 9/14/09 PCP medical records received DOS 9/7/07 to 10/18/07. LABS and DIAGNOSTICS: Urinalysis - Leukocytes trace, (+) nitrite, protein trace. TSH. CBC. CMP.

History: Caesarean section. 9/14/09 PCP medical records received DOS 9/7/07 to 10/18/07. DepoProvera. PAP mild dysplasia.

Prex Illness: Ovarian cyst; Papilloma viral infection; Hypersensitivity. 9/14/09 PCP medical records received DOS 9/7/07 to 10/18/07. Colposco

Prex Vax Illns:

Vaers Id: **356418-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		03-Sep-2009	04-Sep-2009	CA	WAES0908USA05014	04-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphoma

Symptom Text: Information has been received from a health care professional concerning a 19 year old female patient who on an unspecified date was vaccinated with the second dose of GARDASIL. It was reported that after the second dose of GARDASIL she developed lymphoma. It was reported that the parents were trying to associate it with GARDASIL. The patient was no longer a patient with this practice due to her age. It was reported that she was going to an Obstetrician/Gynecologist practice. The outcome of the patient was not reported. Upon internal review lymphoma was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **356422-2 (S)** **Related reports:** 356422-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	22-Mar-2009		11-Mar-2010	18-Mar-2010	--	200903660	18-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0270X		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2669A		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0651X		Right arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Blood test abnormal, Disability, Hypersensitivity, Impaired work ability, Mechanical urticaria, Serum sickness, White blood cell count increased

Symptom Text: This case was received from a health care professional, via another manufacturer (reference number WAES 0906USA00846), on 25 August 2009. "Initial and follow-up information has been received from a nurse practitioner concerning her daughter, a 18 year old female student who on 06-MAR-2009 was vaccinated with her first dose of GARDASIL, 0.5 ml, intramuscularly into her right deltoid (LOT# 661703/0651X) at 10:40 am." "On 03-MAR-2009, the patient was vaccinated with her third dose of VARIVAX (Lot: 659845/0270X) intramuscularly into her right deltoid at 15:00 pm and with her first dose of MENACTRA (lot # U2669AA) intramuscularly into her left deltoid at 15:00 pm. Concomitant therapy included an unspecified birth control pill." "Subsequently the patient had an " allergic reaction, where you could write on her skin with a pen and still see it 3 hours later". However it was not specified if she meant that she could still saw ink on her skin 3 hours later or if she could still saw indentation on her skin 3 hours later. The reporter's daughter also experienced joint pain. The nurse practitioner said that her daughter's allergist thought that it was an allergic reaction to MENACTRA (manufacturer unspecified). At the time of reporting the patient's present status was unknown." "Additional information has been received from the medical assistant and provided the following additional details." "The patient has a past medical history of acne, no known drug allergies." "The exact AE onset date is unknown, but the chart notes show an ER visit on approximately 22-MAR-2009. The patient went into the office on 23-MAR-2009 for blood work (values mostly within normal limits; WBC slightly elevated. The patient was treated with a MEDROL dose pack and Benadryl. The medical assistant couldn't say if the events were disabling or life threatening. The patient's status was unknown." "The health care professional contacted during telephone follow up could not supply the following information: date of event and recovery status." "Additional i

Other Meds: Birth Control Pills

Lab Data:

History: Acne

Prex Illness: Focal seizures

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356427-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		03-Sep-2009	04-Sep-2009	FR	WAES0908USA04734	04-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Adverse reaction

Symptom Text: Information has been received from a (source) via CSL as part of a business agreement (manufacturer control CSL20090828KC1) concerning a 18-26 year old approximately female patient who reported via online survey that on an unspecified date she was vaccinated with the first dose of GARDASIL (Lot number not reported). Subsequently the patient experienced a severe reaction and was hospitalized for a week. The patient stated that she would not care if she missed the next doses of GARDASIL. At the time of reporting on 28-AUG-2009, the patient's status was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356440-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Sep-2009	01-Sep-2009	0	03-Sep-2009	14-Sep-2009	NC		14-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dyspnoea, Heart rate increased, Skin discolouration

Symptom Text: CHILD RETURNED WITH MOTHER ON 9-2-09 DUE TO C/O OF HEART BEATING FAST, DIFFICULTY BREATHING, TURNED GRAY IN THE FACE, AND FELT WEAK. THESE SYMPTOMS OCCURED APPROX. 3 HOURS AFTER RECEIVING THE 2ND GARDASIL INJECTION THE PREVIOUS DAY. WE OBTAINED A PFT, EKG, HGB, BS, AND EXAMINED HER. ALL TESTS WERE NEG AND CHILD LOOKED WELL.

Other Meds: NONE

Lab Data: EKG-NORMAL, PFT-NORMAL, HGB-12.6, RANDOM BS-100

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356448-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Aug-2009	14-Aug-2009	1	03-Sep-2009	14-Sep-2009	VA		14-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1674X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor, Skin discolouration

Symptom Text: Patient claims that she felt lightheaded after standing for 10 mins and she had to be assisted with walking. She also claims that after feeling lightheaded and dizzy she sat down on cold floor at which point "everything was black" for approximately 10-20 mins. Patient never lost consciousness. People with patient noted that she was pale and lips greenish and was sweating profusely.

Other Meds:

Lab Data:

History: HYPOTHYROIDISM

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356454-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Aug-2009	31-Aug-2009	0	03-Sep-2009	14-Sep-2009	IL		15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Syncope, Vaccine positive rechallenge

Symptom Text: patient lying on exam table. While lying on exam table she fainted and arms flailed up. Nurse called patients name and she immediatley opened her eyes and was aware of surroundings. Nurse took pulse, B/P, and resp. All her vitals were within normal limits. Patient had fainted with the first HPV vaccination.

Other Meds: none

Lab Data:

History: no

Prex Illness: none

Prex Vax Illns: fainted~HPV (Gardasil)~1~17~In Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356456-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Sep-2009	03-Sep-2009	0	03-Sep-2009	15-Sep-2009	CA		15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y		Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	UF471AA		Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2992AA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Feeling cold, Pallor

Symptom Text: PT BECAME PALE, WEAK AND DIZZY AFTER ADMINISTERING HPV VACCINE. PT REPORTED FEELING COLD AFTER ADMINISTRATION. PT WAS SITTING AT TIME ON INNOCULATION.

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356460-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Sep-2009	02-Sep-2009	0	03-Sep-2009	15-Sep-2009	CA		15-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334EA		Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2992AA		Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	UF471AA		Right leg	Intramuscular	
VARCEL	MERCK & CO. INC.	0347Y		Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0087Y		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Feeling cold, Pallor

Symptom Text: PT BECAME PALE, WEAK AND DIZZY AFTER ADMINISTERING HPV VACCINE. PT WAS SITTING AT TIME ON INNOCULATION. PT REPORTED FEELING COLD AFTER ADMINISTRATION.

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356463-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jul-2009	03-Sep-2009	64	08-Sep-2009	15-Sep-2009	--		02-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	2	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Blood test normal, Convulsion, Dizziness, Fatigue, Headache, Nuclear magnetic resonance imaging normal, Ophthalmological examination normal, Pain in extremity, Photophobia

Symptom Text: Had seizure approx 1 month after having the 2nd hpv vaccine. since then have been suffering from dizziness, sometimes sore achy left arm. Weakness, fatigue, sensitivity to light, headaches. MRI done and came back clear with "no cause for seizure" seeing Neurologist next week for EEG. Been to doctor and had three sets of blood tests done with no findings. Have had my eyes tested and they came back fine.

Other Meds: monofeme (oral contraceptive)ventolin inhaler (asthma)

Lab Data:

History: asthma.

Prex Illness: Cold during first vaccine - felt fine for 2nd.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356490-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Sep-2009	03-Sep-2009	0	03-Sep-2009	14-Sep-2009	AZ		15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0083Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypotension, Syncope, Unresponsive to stimuli

Symptom Text: Patient had syncopal episode after receiving vaccine and was unresponsive and hypotensive for 5 mins. Patient improved after rest and juice.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356496-1** **Related reports:** 356496-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-Aug-2009	30-Aug-2009	2	03-Sep-2009	14-Sep-2009	VA		15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0311Y	0	Left arm	Intramuscular	
	PPV	MERCK & CO. INC.	0870X	0	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site inflammation, Injection site swelling, Malaise, Pyrexia

Symptom Text: Pt. had generalized reaction at injection site redness, swelling & inflammation. Pt also experienced fever, malaise. Followed up with doctor visit. Events occurred at home.

Other Meds: ALLEGRA D 24 HOUR; DUAC GEL; DIFFEREN GEL

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356496-2** **Related reports:** 356496-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-Aug-2009	28-Aug-2009	0	23-Dec-2009	24-Dec-2009	VA	WAES0909USA00440	28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0311Y	0	Unknown	Intramuscular	
	PPV	MERCK & CO. INC.	0870X	0	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Convulsion, Dizziness, Erythema, Hyperhidrosis, Immediate post-injection reaction, Injection site erythema, Injection site inflammation, Injection site swelling, Malaise, Nausea, Oedema peripheral, Pallor, Pyrexia, Steroid therapy, Syncope, Tremor, Unresponsive to stimuli

Symptom Text: Information has been received from a pharmacist concerning his 19 year daughter who on 28-AUG-2009 was vaccinated with a dose of GARDASIL, 0.5 mL, I.M. and a dose of PNEUMOVAX concomitantly in the same arm. Subsequently, the patient fainted instantly after getting GARDASIL. She regained consciousness and was shaking. She brought to the ER of an unspecified hospital but was not admitted. She seemed to be alright. On an unspecified date, the patient recovered from the AE. The pharmacist also said that, at the time of the report, the patient has "significant swelling" at the site where she was administered PNEUMOVAX. The patient sought unspecified medical attention. Follow-up information was received from the pharmacist via medical records indicating that his daughter was a 19 year old college student with no pre-existing allergies, birth defects or medical conditions (also reported as having asthma). On 28-AUG-2009, at 17:40 (also reported as 17:45), the patient received a first dose of GARDASIL (Lot #659054/0311Y) IM in the left deltoid. On the same day, prior to the GARDASIL injection, the patient received a first dose of PNEUMOVAX (Lot # 661741/0870X) SQ in the left triceps. There was no illness at time of vaccination. Other concomitant therapy included ALLEGRA, DUAC and DIFFERIN. It was reported that the patient immediately became lightheaded, pale and then fainted upon delivery of the GARDASIL almost as soon as the needle was removed (also reported as 17:45). Patient was unresponsive for less than 1 minute. As she was regaining consciousness, she was exhibiting convulsive shaking behavior which prompted the 911 call and an emergency room visit. She was also nauseated, clammy and sweaty. She presented no adverse symptoms at the time when she was vaccinated with PNEUMOVAX. However, on 30-AUG-2009 (also reported at 29-AUG-2009), her arm became very reddened and swollen, accompanied by a high fever which then persisted for 3 days preventing her from leaving for college as planned on 30-AUG-2009. The reaction was d

Other Meds: DIFFERIN; DUAC; ALLEGRA

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356501-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	17-Jun-2009	Unknown		03-Sep-2009	14-Sep-2009	GA	GA09026	23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: No adv s/sx.

Other Meds:

Lab Data: (+) urine HCG (preg. test later performed after vaccine given)

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356502-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jul-2009	01-Jul-2009	0	03-Sep-2009	14-Sep-2009	GA	GA09	15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B031AB	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB236AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Fall, Hypoaesthesia, Hypotonia

Symptom Text: Client reported feeling weak and unable to feel her body. Afterwards client began to fall backwards onto the exam table and was limp for approx. 2-3 seconds. Monitored and applied cool compress to forehead and neck.

Other Meds: None

Lab Data: BP 113/67; HR 68; Resp. 18-20; Pulse Ox 100%

History: Anemia

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356505-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Aug-2009	29-Aug-2009	1	03-Sep-2009	23-Sep-2009	NY		23-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB352EB	0	Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	0914Y	1	Unknown	Subcutaneously	
MNQ	SANOFI PASTEUR	U3018AA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	1522U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blister, Erythema, Local reaction

Symptom Text: Local reaction with varicella vaccine redness/blisters to arm.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356520-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Aug-2009	25-Aug-2009	13	04-Sep-2009	15-Sep-2009	MO		17-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint range of motion decreased, Musculoskeletal disorder, Musculoskeletal pain, Myalgia, Rash, Rash erythematous, Rash maculo-papular, Rash pruritic

Symptom Text: None stated. 9/15/09 PCP Medical records received DOS 8/12/09 to 9/8/09. Assessment: Muscle pain/Myalgia. Patient c/o decreased movement left arm. Point tenderness left shoulder, reduced shoulder flexion, reduced shoulder external rotation. Fine after ibuprofen. Rash on back, chest, breast, axilla. Rash red, raised, itching.

Other Meds:

Lab Data:

History: 9/15/09 PCP Medical records received DOS 8/12/09 to 9/8/09. Eye surgery at 8 months of age.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356522-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Aug-2009	18-Aug-2009	0	04-Sep-2009	15-Sep-2009	OR		16-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2918AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysarthria, Oedema peripheral, Pain in extremity, Pharyngeal oedema, Sinus congestion

Symptom Text: Within 1 hour of receiving the injection, the patient complained of painful arm. Within a few hours, the arm was swollen, more painful and patient complained of sinus congestion, then slurred speech. Mom gave patient BENADRYL, went to ER for a "sense of her throat swelling".

Other Meds:

Lab Data: BP 104/67; HR 58; O2 Sat: 99% on R.A.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356523-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Aug-2009	31-Aug-2009	0	04-Sep-2009	15-Sep-2009	FL		16-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0672Y	0	Left arm	Intramuscular	
FLU	SANOFI PASTEUR	U3190AA	1	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB357CA	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Loss of consciousness, Skin laceration

Symptom Text: Pt passed out while in hall after receiving vaccines. Hit back of head- small 1/4 " laceration. Given juice to drink & allowed to recover with feet up. Sent to ER for stitch eval.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **356529-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Aug-2009	14-Aug-2009	0	04-Sep-2009	15-Sep-2009	NM		16-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Injection site urticaria, Urticaria

Symptom Text: Mother reported hive-like eruption around neck, at injection site, on thighs immediately following injection. Child also stated some difficulty breathing that passed.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 356541-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	16-Sep-2008	16-Sep-2008	0	04-Sep-2009	08-Sep-2009	FR	WAES0810MEX00023	08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Missed labour, Nausea, Urinary tract infection, Vomiting

Symptom Text: Information has been received from a 21 year old female with vulvovaginitis and pyelonephritis (last urinalysis positive in Oct-2008) with a history of papilloma viral infection, loop electrosurgical excision procedure and cervical conisation who in FEB-2008, was vaccinated with GARDASIL first dose, in APR-2008, was vaccinated with GARDASIL second dose and the last dose was received on 16-SEP-2008. Concomitant therapy included GYNOCLINV. The last menstrual period was on 20-AUG-2008. The patient referred that she unknown that was pregnant at the time of the last vaccine. On 29-SEP-2008 blood pregnancy test reported as positive. In Oct-2008 urinalysis was positive for infection. The patient's pregnancy continued with good evolution. Follow up: new information was received. In January 2009, the patient experienced vomiting and nausea and it was necessary to receive rehydration (route not reported) at the doctor's office. The reporter confirmed that hospitalization was not required. The patient recovered from nausea and vomiting in January 2009 and felt that vomiting and nausea were not related to therapy with GARDASIL she stated that her physician considered nausea and vomiting were related with the pregnancy. On 26-AUG-2009 pregnancy outcome information was received from the patient who referred that on 13-MAY-2009 at 38 weeks of pregnancy a cesarean section was performed due missed labor, she delivered a live male infant in healthy conditions and weighing 2.825 kilograms, Apgar is unknown. The patient and her son were discharged on 16-MAY-2009 both without complications. The patient recovered from nausea and vomiting (date unknown). No further information is available.

Other Meds: clindamycin (+) fluocinolone acetonide, 16Sep08-19Sep08

Lab Data: serum beta-human chorionic gonadotropin, 29Sep08, positive for pregnancy; urinalysis, ??Oct08, positive for infection

History: Papilloma viral infection; Loop electrosurgical excision procedure; Cervical conisation

Prex Illness: Pregnancy NOS (LMP= 20Aug08); Vulvovaginitis; Pyelonephritis

Prex Vax Illns:

Vaers Id: **356542-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-May-2009	11-May-2009	0	04-Sep-2009	08-Sep-2009	FR	WAES0908USA04422	08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0506X		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Dry mouth, Erythema, Eyelid oedema, Flushing, Headache, Lip dry, Lip swelling, Malaise, Mobility decreased, Muscle spasms, Muscular weakness, Ocular hyperaemia, Oedema mouth, Pain, Paraesthesia, Pollakiuria

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail concerning a 12 year old female patient who on 11-MAY-2009 was vaccinated with a dose of GARDASIL (Lot # 661702/0506X, Batch # K6310). On 11-MAY-2009 the patient experienced headache, asthenia, dry mouth, erythema, eyelid oedema, lip dry, lip swelling, muscle spasms, ocular hyperaemia and paraesthesia and was hospitalized. Approximately one hour after vaccination, the patient developed headache, facial flushing, paraesthesia over whole body, weakness in her left leg, shooting pains from heal up her legs. The next day the patient was unwell and developed severe cramping in the thigh. The patient was taken to ED, the patient was unable to move and was in pain, the patient was able to stagger. Later, the patient developed puffy eyelids, red eyes, swollen and dry lips/mouth. The patient seemed to be urinating excessively. Prior to vaccination, the patient had a suspected viral illness but had recovered prior to vaccination. At the time of the report, the patient was still recovering but had not yet recovered. The patient was sore and had still legs, patient was able to walk unassisted and was experiencing pins and needles in feet and occasionally in the hands. The doctors stated that there were signs of questionable rheumatoid arthritis. The patient's father had nephrotic syndrome at 11 years old of age. The agency felt that headache, asthenia, dry mouth, erythema, eyelid oedema, lip dry, lip swelling, muscle spasms, ocular hyperaemia and paraesthesia were possibly related to vaccination with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 356543-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-May-2009	28-May-2009	0	04-Sep-2009	08-Sep-2009	FR	WAES0908USA04439	08-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Chest discomfort, Dyspnoea, Headache, Inappropriate schedule of drug administration, Insomnia, Loss of consciousness, Panic attack, Syncope, Tremor

Symptom Text: Information was obtained on request by the company from the agency via a public case detail concerning an 18 year old female patient who on 28-MAY-2009 was vaccinated with the second dose of GARDASIL. This was one month after first vaccination (did not know why there was an interval of only one month between instead of two months). On 28-MAY-2009 the patient experienced syncope, anxiety, chest discomfort, dyspnoea, headache, insomnia and panic attack. Ten minutes after injection the patient fainted, developed headache and continued to black out over next few days. Two weeks ago (about mid-June), the symptoms worsened, headache increased. The patient had trouble breathing and experienced panic attacks. The patient developed uncontrollable shaking of arms and was hospitalized. Valproate was prescribed but ceased after 2 days. Magnetic resonance imaging indicated no abnormalities, an electroencephalography showed an already dysrhythmia (possibly due to febrile convulsions as a toddler). The patient was discharged from hospital with recommendation for psychiatric assessment which, at this stage, had not been acted upon. The patient continued to experience a feeling of pressure on chest, difficulty breathing, anxiety and insomnia. The agency considered that syncope, anxiety, chest discomfort, dyspnoea, headache, insomnia and panic attack were possibly related to vaccination with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 15?Jun09, no abnormalities; electroencephalography, 15?Jun09, already existing dysrhythmia

History: Febrile convulsion

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356566-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Sep-2009	04-Sep-2009	0	04-Sep-2009	17-Sep-2009	MI		09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1577X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Affect lability, Fall, Head injury, Headache, Irritability, Local swelling, Loss of consciousness, Neck pain, Pain of skin, Skin injury, Syncope

Symptom Text: Patient received Gardasil HPV vaccine. After receiving vaccine patient was standing and waiting to sign in for blood work when she passed out, falling straight back, hitting head on floor (cement with indoor/outdoor carpet). Pt. had brief loc per mom and tech. On arrival of RN patient was alert complaining of severe head and neck pain. 911 was called and patient was transferred to ER. 9/16/09 ER records received DOS 9/4/09. Assessment: Vasovagal Syncope. Fell and hit head after standing up. Lost consciousness for 30 seconds. Some confusion. Pain in back of head. Concerned she may be pregnant. Tenderness and swelling posterior scalp. Labile affect with irritability.

Other Meds: 9/16/09 ER records received DOS 9/4/09. Trileptal, Abilify, Lamictal.

Lab Data: 9/16/09 ER records received DOS 9/4/09. LABS and DIAGNOSTICS: CBC - Neut 77.2% (H) Lymph 17.3% (L). CHEM - ALK 87 U/L (L). Urinalysis - protein 10 mg/dL (H). Pregnancy Screen Urine (-).

History: Lamictal. 9/16/09 ER records received DOS 9/4/09. Asperger, attention deficit hyperactivity disorder, mood disorder. Previous adverse reactions to vaccines.

Prex Illness:

Prex Vax Illns:

Vaers Id: **356573-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	05-Oct-2007	25-Nov-2007	51	04-Sep-2009	17-Sep-2009	KY		01-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	12228AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1063V	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0797V	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	02442AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Body tinea, Dyskinesia, Fatigue, Headache, Insomnia, Migraine, Myalgia, Pain in extremity, Paraesthesia, Pharyngitis, Pharyngitis streptococcal, Tremor, Upper respiratory tract infection, Vision blurred, Vomiting, Weight decreased

Symptom Text: Gardasil #1, Hep A #1, Menactra and flu given 10/5/07. Patient seen 5/12/08 and reported vomiting several times a week since thanksgiving (about 6-7 weeks after vaccine), limb pain, parasthesia's, headaches and fatigue. Patient still nearly 2 years later with vomiting several times a week, leg pain and tremors in her right hand/arm bad enough to interfere with school work and writing. She has had extensive GI and neuro evaluation with no diagnosis and no satisfactory treatment of symptoms. We do not know if this is related to gardasil but have begun to question it. She had a second gardasil 7/21/08. Of note, this patient has a sister with a severe mitochondrial disorder affecting her gut function, seizures, deteriorating mental function. 9/14/09 MR received from pcp which include multi-specialty consults dated from 10/2007 to 9/2009. In for WCC 10/5/07 with dx: Well. 4 vax given. Multiple visits after for pharyngitis, URI, tinea corporis, vomiting x 6 months with 8 lb weight loss, H/A, blurry vision, lower limb pain, decreased sleep, strep throat. Dx: Migraine/vomiting weight loss. Referred for labs and consults. By 9/3/09 reporting continued vomiting, tremors, muscle pain. GI consult with no specific dx made. 6/16/09 reports worsening of sx. PE (+) for fine tremor of tongue and hands. Neuro consult 6/29/09 with impression: Migraine complex. Returned for w/u for possible seizures due to episodes or tremors and jerking of the R side.

Other Meds: micronor at time of vaccination. Now on lo ovral, ponstel, zofran, carafate, lactaid, prilosec, amitryptyline

Lab Data: carnitine level low, scope nl, fasting blood sugar, b12, folate, heavy metal screen, sleep study, ekg all nl as far as I know. EEG abnl--getting further studies. Labs and diagnostics: MRI head (-). Upper GI with small bowel WNL. EGD WNL

History: menorrhagia. PMH: Menorrhagia. ankle pain.

Prex Illness: well

Prex Vax Illns: none~ ()~~0~Patient|none~ ()~~0~Sibling

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356575-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Sep-2009	01-Sep-2009	0	04-Sep-2009	17-Sep-2009	CO		10-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aphasia, Confusional state, Dizziness, Glossitis, Malaise, Migraine, Nausea, Speech disorder, Tongue geographic

Symptom Text: Father states that his daughter became ill the next day after vaccination. Within 24 hours he was nauseated and dizzy. She has what is called migratory glossitis or geographic tongue. He provided pictures of her tongue, which had a red irregular border. This occured two days ago, unknown if patient has improved, asked parent to call to advise us of condition. 10/22/09: Emergency Room records received for date of service 5/25/08. Dx: Migraine headache with aphasia. Assessment: Presented to the ER with a severe headache, confusion, speech making no sense and unable to follow directions. No history of head trauma. Given fentanyl and became drowsy. MRI and CT of head both negative, CSF Gram stain negative. Drug screen was negative. Plan was for EEG on an outpatient basis. Left ER able to stand, walk, strength equal, reflexes were brisk, equal and symmetrical. No mention is made of any abnormality of the tongue upon examination.

Other Meds:

Lab Data: 10/22/09: Emergency Room records received for date of service 5/25/08. Labs and Diagnostics: MRI of brain Normal, CT of the head Normal. Hgb 15.1 (H), Lymphocytes 42 (H), Monocytes 13 (H), CO2 21 (L), Alk. Phos. 285 (H). Urine drug scr

History: 10/22/09: Emergency Room records received for date of service 5/25/08. PMH: None. Mother and Grandmother with history of migraines.

Prex Illness:

Prex Vax Illns: severe migraine requiring ER visit.~HPV (Gardasil)~1~13.80~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356582-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Aug-2008	04-Aug-2008	0	05-Sep-2009	15-Sep-2009	FL		05-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain lower, Chest pain, Constipation, Cough, Crying, Headache, Nausea, Pain, Screaming, Tremor, Vaccination complication

Symptom Text: After recieving the Gardasil vaccine, about 3-4 ours later she had severe abdominal pain that did not stop. I gave her motrin but it didnt help. After she begain to yell, I drove her to hosp. The ER Docs refused to think Gardasil had anything to do with her pain because they claim to have never heard of such an event happening with a patient before. I happen to disagree with them. 9/28/09 ER records received DOS 8/4/09 to 8/5/09. Assessment: Chest pain, abdominal pain, allergic reaction to Gardasil. Patient c/o stabbing pain in middle of chest. Hurts with movement. Cough. Stabbing abdominal pain. Headache, nausea, "shakes", crying. Abdominal gas and distention as etiology for pain. Chest pain now resolved. Patient in no distress. 9/28/09 Received ICD9 codes: 786.59; 789.00; V14.0./ss

Other Meds: none

Lab Data: They diagnosed her with constipation & pain in lower abdomen. This is not a correct diagnosis, my daughter was not constipated. She did eat any thing after 12 pm. 9/28/09 ER records received DOS 8/4/09 to 8/5/09. LABS and DIAGNOSTICS: EKG

History: none. 9/28/09 ER records received DOS 8/4/09 to 8/5/09. Penicillin Allergy.

Prex Illness: none- she went in for annual school check-up

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356590-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Jan-2008	15-Jul-2008	183	06-Sep-2009	11-Sep-2009	--		15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	UNK

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Rheumatoid arthritis

Symptom Text: My daughter was adminstered GARDASIL (I cannot find it in your list of vaccines below/ Ch.-B.: NE51780, NE51790, NF56940) on May 5, 2007, July 10, 2007, and January 14, 2008. A few months later (middle of 2008) she began to complain about joint pains that have now been diagnosed officially as rheumatoid arthritis. She has never been exposed to cigarette smoking, no alcohol or drug abuse or any other behavior that might have triggered the disease. Her maternal grandmother was diagnosed with it in her mid-40's, but she used to be a heavy smoker, and only has a light bought. Again, I cannot think of any other external trigger that might have been responsible for the illness other than the questionable Gardasil immunization, because it is closely related in time: shortly after the immunization the arthritis broke out.

Other Meds: None at the time

Lab Data: The RA diagnosis has been established (after examination and blood tests) on July 22, 2009 by Dr. at the Hospital

History: Hashimoto (Thyroid)

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356600-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-Sep-2009	03-Sep-2009	1	07-Sep-2009	17-Sep-2009	NC		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Feeling abnormal

Symptom Text: Gardasil vaccinations administered @ 4:30 p.m. 9/2/2009, was taken by ambulance to Hospital, @ 7:00 am on 29/3/2009. Diagnoses, seizure. 10/7/09 ER record received for date 9/3/09. Pt presented to ER with complaint from Mother that pt had 3 seizures while in shower and was "odd" for 5 minutes. Had HPV vaccine previous day. 12/17/09 GYN records received for DOS 9/02/09. Pt. presents for routine exam. YAZ prescribed. Gardasil Vax provided. Assessment: dysmenorrhea.

Other Meds: None

Lab Data: Seizure 10/7/09 ER record received for date 9/3/09 Diagnostics/Lab: CT scan of head, UA.

History: None

Prex Illness: None

Prex Vax Illns: Seizure~HPV (Gardasil)~3~16.00~Patient

Vaers Id: **356610-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-Aug-2009	29-Aug-2009	0	04-Sep-2009	16-Sep-2009	WA		16-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0492Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0572X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Local reaction, Oedema peripheral, Pruritus, Pyrexia

Symptom Text: Local reaction (R) arm, red, swollen & itchy. Slight fever x2 days. Tx: Ice, TYLENOL and BENADRYL. F/u in office PRN.

Other Meds: None

Lab Data:

History: None known

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356613-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Sep-2009	03-Sep-2009	0	04-Sep-2009	16-Sep-2009	IA		16-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB350BA	0	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	U3019AA	0	Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	0731Y	1	Unknown	Subcutaneously	
HPV4	MERCK & CO. INC.	0216Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt's parent reports pt fainted while at band practice at school approx. 3 1/2 hrs after immunizations were given.

Other Meds: none

Lab Data:

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **356614-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Sep-2009	03-Sep-2009	2	04-Sep-2009	16-Sep-2009	GA		31-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0216Y	0	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U3012AA	0	Right arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041CA	0	Left arm	Unknown	
VARCEL	MERCK & CO. INC.	0806Y	1	Right arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB327AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site warmth, Oedema peripheral, Pain in extremity, Pruritus

Symptom Text: Pt. complains of pain and swelling in hands and feet. Both vaccination sites still warm to touch. I noted on 9/15/09 mother of child, she had yes recovered. 9/9/09 Spoke with pt who did not see any treating MD, took ibuprofen and Benadryl as advised by HD, pt still has slight itching but is improving. No f/u required. Case closed.

Other Meds: No

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

Vaers Id: 356630-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Sep-2009	03-Sep-2009	0	04-Sep-2009	17-Sep-2009	WI		17-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0940X	0	Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB287AB	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Dry skin, Dysarthria, Dyspnoea, Fatigue, Feeling abnormal, Feeling hot, Hyperhidrosis, Muscle spasms, Nausea, Paraesthesia oral, Pulse abnormal, Skin warm

Symptom Text: 10:05A - received vaccines shortly after got nauseated, warm. Dizzy - laid in supine position. Ice to back of neck. BP (L) arm sitting 104/60 pulse 60 slightly thready. Skin warm & dry palms sweaty/clammy. After 15-20 min c/o trouble getting breath, tongue feeling funny, general feeling "feeling funny", unable to describe. Mid chest became red in color - lacy looking at this time. Client c/o again of not being able to get breath, speech somewhat slurry & thick sounding - E vehicle called. B/P 106/68 Pulse continues to be slightly thready but 60-60 in number. Feeder were evaluated. Skin dry, palms of hands sweaty. Rash after approx 5 min decreased in intensity. Continues to c/o of feeling weird, but unable to describe feelings. Throughout this event client continued to have "spasms of legs, arms & lips - denied being cold. Transported by E-vehicle to hospital. 9-4-09 9AM TC to parent. Patient is tired, but has been taking BENADRYL. No rash at this time. Eating & drinking. Slept most of yesterday. Taking ibuprofen also for c/o HA & sore arm.

Other Meds: BCP

Lab Data: E Room gave IV BENADRYL - no rash present

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356640-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Sep-2009	04-Sep-2009	1	04-Sep-2009	30-Sep-2009	PA		16-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2874BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	02494	2	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0858Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Seen @ 48 hours ago - got 3 shots GARDASIL, VARICELLA, MENACTRA.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **356645-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Oct-2008	07-Oct-2008	0	08-Sep-2009	09-Sep-2009	--	WAES0810USA04754	09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Labour complication

Symptom Text: Information has been received from an 18 year old healthy female who on 13-OCT-2008 was vaccinated with the first dose of GARDASIL (Lot # 660393/0067X) and was about 4 weeks pregnant at the time (LMP approximately 15-SEP-2008). Estimated delivery date: 22-Jun-2009. No adverse event reported. The patient did not seek medical attention. Follow-up information was received from the registered nurse indicating that the outcome pregnancy questionnaire was forwarded to the OB/GYN who is currently seeing the patient. Follow up information was received from the registered nurse for the pregnancy registry for GARDASIL who reported that on 10-JUN-2009, the patient gave birth to a normal male infant weighing 6 pounds and 6 ounces, length 19 and head circumference 12 3/4. There were no other complications or abnormalities. It was reported that during pregnancy there were no complications. Other medication used during pregnancy included prenatal vitamins (everyday). No diagnostic tests were performed during pregnancy. During labor/delivery, the patient did not dilate and required a c-section. Upon internal review, did not dilate and required a c-section was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 9/15/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356646-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Oct-2008	01-Nov-2008	16	08-Sep-2009	09-Sep-2009	FR	WAES0812USA02673	09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0251U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Arrested labour, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a gynecologist that concerning an 18 year old female who on 16-OCT-2008 was vaccinated with GARDASIL (lot number 0251U; batch number NF43780) toleration was not reported). The patient was vaccinated while pregnant (gestation week not reported) with a second dose of GARDASIL (lot number 1477U; batch number NH25390) route, injection site not reported; on 10-NOV-2008 in approximately 4th week of pregnancy. On 23-NOV-2008 sonography revealed pregnancy (gestation week 8 to 9). Prior the patient was presented to an internist due to abdominal pain which was diagnosed as pregnancy. The patient's menstrual cycle had been irregular therefore the date of the last menstrual period (LMP) was unknown. The calculated end of pregnancy would be approximately 30-JUN-2009. At the time of reporting the pregnancy was without pathologies and the patient had not experienced many adverse effects. Follow up information has been received on 31-AUG-2008. Due to cesarean section the case had to be upgraded to serious. It was reported that the course of pregnancy was normal. The delivery was by cesarean section to arrested labor during stage of expulsion on 09-JUL-2009. The prenatal examination of mother and child showed no pathologies. Other business partners included are: E2008-10928. The reporter felt that the Arrested labour was an important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 23Nov08, pregnancy-gestation was week 8-9

History:

Prex Illness: Pregnancy NOS (LMP = 23Sep08)

Prex Vax Illns:

Vaers Id: **356647-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Oct-2007	26-Nov-2007	28	08-Sep-2009	09-Sep-2009	FR	WAES0908USA04428	09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Arthralgia, Bedridden, Chills, Condition aggravated, Fatigue, Hallucination, Headache, Hyperhidrosis, Influenza like illness, Malaise, Musculoskeletal stiffness, Oropharyngeal pain, Petechiae, Photophobia, Pyrexia, Rash, Rheumatoid arthritis, Stills disease adult onset, Vomiting, Weight decreased

Symptom Text: Information has been received on request by the company from the agency via public case details form concerning a 16 year old female patient who on 11-MAY-2007 was vaccinated with the first dose of GARDASIL (Lot number 655742/0138U and Batch number J0799) intramuscular, on 12-JUN-2007 with the second dose of GARDASIL and on 29-OCT-2007 with the third dose of GARDASIL (Lot number not reported). On 26-NOV-2007 the patient experienced rheumatoid arthritis and still's disease adult onset. The first episode of illness resulted in general malaise and flu like symptoms and progressed to cyclical pattern of fevers/chills/sweats several times, during 24 hours period. This first episode of illness resolved around 09-DEC-2007 and patient recovered. The patient was taken to a medical centre during this illness. The second episode of illness was very severe and began on 22-DEC-2007 and again started with malaise and flu like symptoms progressing to a continuous cycle if fevers/chills/sweats with no break between the cycles. The patient had severe abdominal and joint pain, sore throat, headache, vomiting and was incapacitated and continually bedridden and unable to attend to ADL's such as showering and eating for two weeks. The patient also suffered from hallucinations and lost 6 kg. The patient again attended a medical centre for treatment. In January 2007, the patient was admitted to the hospital for 5 days under specialist care. The patient was then referred to another specialist (Rheumatologist) and registered and had been under their care since February 2008. A firm diagnosis had not been reached to date, however the specialist had started that it appeared to resemble adult onset still's disease. It was unsure if the following information was relevant, but the patient the patient suffered a mild fever after the first dose of GARDASIL in May 2007. The patient also suffered an illness in mid July 2007. The symptoms of the illness involved high fever, severe headache, neck stiffness, extreme aversion to light, vomiting and p

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Hallucination

Prex Vax Illns:

Vaers Id: **356648-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Apr-2009	27-Apr-2009	0	08-Sep-2009	09-Sep-2009	FR	WAES0908USA05097	09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Headache, Lymphadenopathy, Muscular weakness, Paraesthesia

Symptom Text: Information was obtained on request by the company from the agency via a Case Line Listing through CSL NZ as part of a business agreement (Manufacturer control number: 084849), concerning a 16 year old female patient who on 27-APR-2009 was vaccinated with 0.5 ml of a dose of GARDASIL intramuscularly. On 27-APR-2009 the patient experienced paraesthesia (severe), lymphadenopathy (severe), arthralgia (severe), headache (severe) and muscle weakness (severe). At the time of reporting in June 2009, the patient's paraesthesia, lymphadenopathy, arthralgia, headache and muscle weakness persisted. The agency considered that paraesthesia (severe), lymphadenopathy (severe), arthralgia (severe), headache (severe) and muscle weakness (severe) were "possible" related to therapy with GARDASIL. Paraesthesia (severe), lymphadenopathy (severe), arthralgia (severe), headache (severe) and muscle weakness (severe) were resulted in persisting disability. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356649-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	14-Jul-2009	31-Aug-2009	48	08-Sep-2009	09-Sep-2009	--	WAES0909USA00007	09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse in the physician's office concerning a female patient who on 14-JUL-2009 was vaccinated with the second dose of GARDASIL (lot# 661531/1311X). On 31-AUG-2009 the patient "experienced a seizure approximately 6 weeks after receiving her second dose of GARDASIL. She went to the emergency room but it was unknown if she was admitted to the hospital. " The result of computed axial tomography was normal. The outcome was unknown. Follow up information was received from a Certified Medical Assistant (C.M.A.) on 01-SEP-2009 via telephone stated that the 10 year old patient received the first dose of GARDASIL on 04-MAY-2009 (Lot number not available to reporter at that time) and second dose of on 14-JUL-2009 (lot# 661531/1311X). On 31-AUG-2009, the patient had a seizure. The patient's mother took the patient to the Emergency Room. The patient had a CT scan of the head which was normal. The patient was not admitted to the hospital. The patient was scheduled for an EEG on 03-SEP-2009. The Certified Medical Assistant did not know if the patient recovered and did not know if the patient had a significant disability. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: head computed axial, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 356650-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Jun-2009	06-Jul-2009	35	08-Sep-2009	09-Sep-2009	OH	WAES0909USA00201	21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Deep vein thrombosis, Phlebitis superficial, Thrombophlebitis superficial, Thrombosis

Symptom Text: Information has been received from a 24 year old female with family history of blood clots, her grandmother and mother were factor 5, and no drug reactions/allergies who in April 2009, was vaccinated with the first dose of GARDASIL (Lot # not reported). In June 2009, the patient was vaccinated with the second dose of GARDASIL (Lot # not reported). Concomitant therapy included hormonal contraceptives (unspecified). On 06-JUL-2009, the patient was diagnosed with a blood clot and was admitted to the hospital for less than 1 day. On an unspecified date, the patient had a factor 5 test and an ultrasound performed (results not provided). In the end of July 2009, the patient recovered from blood clot. Additional information has been requested. 9/18/09 Hospital records received DOS 7/8/09 to 7/9/09. Assessment: Acute deep venous thrombosis in right leg. Soft ball injury to leg, multiple abrasions 1 week prior. Presents with exquisite right calf pain. Superficial phlebitis of right lesser sapheous, occluded calf vein, thrombosis of right gastronemius vein, occluded deep vein thrombosis of right superficial femoral and popliteal veins. ICD-9 Codes: 782.3 Edema, 451.0 Superfic Phlebitis - Leg, 916.0 Abrasion Hip & Leg, 346.90 Migrne Unsp wo Ntrc Mgrn, V18.3 HX-Blood Disord Nec.

Other Meds: hormonal contraceptives. 9/18/09 Hospital records received DOS 7/8/09 to 7/9/09. Oral contraceptives.

Lab Data: Ultrasound, ?/?/09, results not provided; Factor V activity test, ?/?/09, results not provided. 9/18/09 Hospital records received DOS 7/8/09 to 7/9/09. LABS and DIAGNOSTICS: Venous Duplex - Abnormal. CBC - WBC 12.8 K/uL (H). Heterozygous

History: Unknown. 9/18/09 Hospital records received DOS 7/8/09 to 7/9/09. Migraine headaches, generalized anxiety disorder, depression, allergic rhinitis. Alcohol use. Factor V Leiden deficiency.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356651-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		08-Sep-2009	09-Sep-2009	--	WAES0909USA00202	09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a office nurse concerning a 15 year old female. The nurse reported that the patient who was not a patient of the office nurse, but was her daughters best friend, was vaccinated with the first dose of GARDASIL and right after receiving the vaccine the patient experienced seizures. The outcome of the event was unknown. Upon internal review, seizure was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 356653-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Jan-2009	01-Apr-2009	90	08-Sep-2009	09-Sep-2009	--	WAES0909USA00324	21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain upper, Chest discomfort, Chest pain, Metabolic syndrome, Pulmonary embolism

Symptom Text: Information has been received from a health professional concerning an 18 year old female patient who in January 2009, was vaccinated with a dose of GARDASIL (the patient was not vaccinated at the reporter's clinic). The consumer became their patient because of the pulmonary embolism diagnosed shortly after getting GARDASIL in April 2009. The patient was treated with COUMADIN for 3 months, but then she was on aspirin daily. She has been hospitalized on several occasions due to her pulmonary embolism (one reported hospitalization lasting 10 days). It was reported that there were no other risks identified for the pulmonary embolism. At the time of the report, the patient status was unknown. The reporter considered the pulmonary embolism to be immediately life-threatening. Additional information has been requested. 9/18/09 Hospital/medical records received DOS inpatient 4/16/09 to 4/17/09 and outpatient visits to 8/24/09. Assessment: Pulmonary embolism and infarction. Dysmetabolic syndrome X. Patient presents with upper abdominal pain and lower chest type symptoms. Pulmonary emboli. Chest pain. ICD-9 Codes: 415.19 Pulmonary embolism and infarction. 277.7 Dysmetabolic syndrome X.

Other Meds: Unknown

Lab Data: Unknown. 9/18/09 Hospital/medical records received DOS 4/16/09 to 8/24/09. LABS and DIAGNOSTICS: CBC - WBC 11.6 K/MM3 (H) Lymph 25.4% (L). Urinalysis - Blood 2+ (H) RBC (+) Bacteria (+) Urobilinogen 2.0 EU/DL (H). CHEM - K 3.4 MEQ/L (L) Glu

History: Unknown. 9/18/09 Hospital/medical records received DOS 4/16/09 to 8/24/09. Obesity. Insulin resistance syndrome. Diabetes mellitus. Hypothyroid.

Prex Illness:

Prex Vax Illns:

Vaers Id: **356660-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-May-2009	27-Jul-2009	81	08-Sep-2009	09-Sep-2009	FR	WAES0908USA05040	09-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Alopecia

Symptom Text: Information was obtained on request by the company from the agency via a Case Line Listing through CSL as part of a business agreement, concerning a 17 year old female who on 07-MAY-2009 was vaccinated with 0.5 ml of a dose of GARDASIL intramuscularly. Concomitant therapy included fluticasone and albuterol. On 27-JUL-2009 the patient experienced alopecia (not severe). At the time of the report patient's alopecia (not severe) persisted. The agency considered that alopecia was unlikely related to therapy with GARDASIL. Alopecia (not severe) was considered to be disabling. The original reporting source was not provided. Additional information is not expected.

Other Meds: albuterol; fluticasone

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **356662-1 (S)** **Related reports:** 356662-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Feb-2008	11-Feb-2009	366	08-Sep-2009	14-Sep-2009	PA		23-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	2	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain upper, Arterial occlusive disease, Cardiac operation, Chest pain, Dyspnoea, Dyspnoea at rest, Dyspnoea exertional, Endarterectomy, Haemoptysis, Intracardiac thrombus, Joint injury, Lymphadenopathy, Oral contraception, Palpitations, Productive cough, Pulmonary embolism, Pulmonary infarction, Tachycardia, Tachypnoea, Vena cava thrombosis

Symptom Text: Onset of chest pain, SOB, cough - 2/09. CT chest 2/11/09 - R pulmonary artery occlusion secondary to massive PE. 2/12/09 R atriotomy removal of R atrial mass. 9/11/09 Hospital records received DOS 2/11/09 to 2/17/09. Assessment: Pulmonary embolism/right atrial thrombus. Birth control pill initiated 2-3 months prior. Cough with sputum production past month and a half. Hemoptysis with palpitations. Injured knee 4 days ago. 2 days ago suddenly became short of breath, persisted at rest and with exertion. Patient presents with dyspnea at rest. Sharp chest discomfort anteriorly over sternal area. Tachycardia, tachypnea, epigastric tenderness. Mild adenopathy. Right atriotomy and removal of right atrial mass. Right pulmonary thromoendarterectomy. Massive occlusive pulmonary embolus with suspicion of pulmonary infarct. Thrombus in left inferior vena cava. 9/22/09-ICD-9 codes received-429.89, 415.19, 287.5, 285.1, 286.9, 453.2, 416.8, 785.0, 785.6, 722.10, 447.6, V183, V1200 and V586.9.

Other Meds: none

Lab Data: 2/11/09, CT chest; 2/11/09, D dimer 1960. 9/11/09 Hospital records received DOS 2/11/09 to 2/17/09. LABS and DIAGNOSTICS: Echocardiogram - abnormal. CT Abdomen, chest, pelvis - Abnormal. Heart Rate 107 - 123 min. Chloride 100 (L). CBC - WBC

History: bee sting allergy; L5-S1 disc herniation; Lyme 8/06. 9/11/09 Hospital records received DOS 2/11/09 to 2/17/09. Lyme disease. Herniated disc. Burns to fingers of left hand. Allergic to bee stings. Alcohol use.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **356662-2 (S)** **Related reports:** 356662-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Feb-2008	11-Feb-2009	366	19-Nov-2009	20-Nov-2009	--	WAES0911USA01048	20-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	2	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Arterial occlusive disease, Chest discomfort, Chest pain, Cough, Dyspnoea, Dyspnoea at rest, Dyspnoea exertional, Endarterectomy, Epigastric discomfort, Haemoptysis, Intracardiac thrombus, Joint injury, Lymphadenopathy, Palpitations, Productive cough, Pulmonary embolism, Pulmonary infarction, Tachycardia, Tachypnoea, Vena cava thrombosis

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 15 year old female with allergic reaction to bee sting, herniated disc, lyme disease, alcohol use and pain in fingers, was vaccinated IM with the third dose of GARDASIL (lot # 658558/1061U) into her right arm on 11-FEB-2009. In February 2009, the patient experienced chest pain, short of breath and cough. On 11-FEB-2009, chest computed axial tomography (CT) was performed with right pulmonary artery occlusion secondary to massive pulmonary embolism (PE). On 11-FEB-2009, patient's D-dimer was 1960. The patient was hospitalized. On 12-FEB-2009 right atriotomy removal of right atrial mass. On 11-SEP-2009 Hospital records received from 11-FEB-2009 to 17-FEB-2009. Assessment: Pulmonary embolism/right atrial thrombus. Birth control pill initiated 2-3 months prior. Cough with sputum production past month and a half. Hemoptysis with palpitations. Injured knee 4 days ago. 2 days ago suddenly became short of breath, persisted at rest and with exertion. Patient presents with dyspnea at rest. Sharp chest discomfort anteriorly over sternal area. The patient experienced achycardia, tachypnea, epigastric tenderness. Mild adenopathy. Right atriotomy and removal of right atrial mass. Right pulmonary thromoendarterectomy. Massive occlusive pulmonary embolus with suspicion of pulmonary infarct. Thrombus in left inferior vena cava. Echocardiogram was abnormal. Abdomen, chest, pelvis CT abnormal. Heart rate 107-123/min, chloride 100 (L). On 22-Sep-2009, ICD-9 codes received-429.99. 415.19. 287.5. 286.9. 453.2. 416.8. 785.0. 785.6. 722.10. 447.6. V183. V1200 and V586.9. The listing indicated that one or more of the events was considered to be immediately life-threatening. No further information is available. The original reporting source was not provided. The VAERS ID number is 356662. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were

Other Meds: Unknown

Lab Data: chest computed axial, 02/11/09, right pulmonary artery occlusion secondary to massive PE; electrocardiogram, abnormal; chest computed axial, abnormal; abdominal computed, abnormal; plasma D-dimer test, 02/11/09, 1960; total heartbeat count,

History:

Prex Illness: Allergic reaction to bee sting; Herniated disc; Lyme disease; Alcohol use; Pain in fingers

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356674-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Aug-2009	01-Sep-2009	4	08-Sep-2009	18-Sep-2009	NM		18-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis allergic, Urticaria

Symptom Text: Developed severe and prolonged allergic rash/hives required multiple office visits/medication.

Other Meds: None

Lab Data: Allergic reaction

History: Allergy to shellfish; Hx asthma

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356676-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	03-Sep-2009	03-Sep-2009	0	08-Sep-2009	18-Sep-2009	NJ		18-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	02164	1	Right leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives

Other Meds: Pt takes YAZ

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356683-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Sep-2009	01-Sep-2009	0	08-Sep-2009	18-Sep-2009	NY		23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	132058A		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0229X		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt was given GARDASIL and ADACEL 100m /office approximately 10 minutes after injection, was found outside the building by police. Had syncope.

Other Meds:

Lab Data:

History: Asthma

Prex Illness: WCE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356699-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Aug-2009	21-Aug-2009	10	08-Sep-2009	18-Sep-2009	OH		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB312AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Lymphadenopathy

Symptom Text: 9-3-09 Rec'd T/C from MGM, advised client developed enlarged node Left side of her neck,close to the clavicle on 8-21-09. States client has been very tired but has been going to school. MGM stated client did not have any fever, sore throat or headache. PHN advised MGM to take client to Urgent Care, as she does not have a PCP.

Other Meds:

Lab Data: 9-8-09 T/C to parent, states she has not taken client to Urgent care due to cost. State she doesn't have a PCP, doesn't qualify for assistance, state there is no Free Clinic. PHN strongly enc. parent to have client seen by a physician. Gave

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356716-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	31-Aug-2009	31-Aug-2009	0	08-Sep-2009	18-Sep-2009	CO		12-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dizziness, Dyspnoea, Flushing, Headache, Hypoaesthesia, Nausea, Syncope

Symptom Text: Headache, dizziness and shortness of breath following vaccine, then left sided numbness to ear, face, hand and arm x 1 week. 1/5/2010 ED records for 9/8/2009, patient with c/o's left facial and arm numbness, neuro exam wnl 1/5/2010 ED records for 9/9/2009, patient with c/o's lightheadedness, nausea, dull chest pain, felt flushed and faint, Impression Near syncope

Other Meds: None

Lab Data: Labs fingerstick bs wnl Dx studies: CT Head wnl Labs: HCG neg, d-dimer wnl Dx studies: EKG wnl

History: None PMH: Thrombocytopenia Allergies: NKDA

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356750-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	19-Sep-2008	31-Oct-2008	42	09-Sep-2009	10-Sep-2009	--	WAES0905USA01040	10-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a registered nurse certificated concerning a 22 year old female patient with no significant past medical history and no concurrent medical conditions who on 19-SEP-2008 was vaccinated with the first dose of GARDASIL (Lot # 660620/0571X). No concomitant medication was reported. On 19-NOV-2008 was vaccinated with the second dose of GARDASIL (Lot # 661044/0548X). On 20-JAN-2009, an ultrasound was performed for dating which showed single live intrauterine pregnancy (SLIUP), 12 weeks, 2 days. (LMP 31-OCT-2008, EDD 07-JUL-2009). A MSAFP was declined by the patient. Follow up information was received from a registered nurse certified. She reported that on 08-AUG-2009, at 40 1/7 weeks from LMP, the patient gave birth to a normal male infant with no congenital anomalies weighing 8 pounds and 0 ounces, apgar score 9/9. It was reported that the patient required a c-section for fetal bradycardia due to cord compression (cord pH 7.257). There were no other complications during pregnancy neither infections nor illnesses. Laboratory testing during pregnancy included routine screening (results not provided). Upon internal review c-section, fetal bradycardia and cord compression were determined to be other important medical events. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, 01/20/09, Single Live Intrauterine Pregnancy, 12 weeks, 2 days; diagnostic laboratory, 08/08/09, Cord pH 7.257; Apgar score, 08/08/09, 9/9

History:

Prex Illness: Pregnancy NOS (LMP = 10/31/2008)

Prex Vax Illns:

Vaers Id: 356751-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Nov-2007	01-Feb-2008	66	09-Sep-2009	10-Sep-2009	FR	WAES0907USA02391	10-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0276U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Neurodermatitis, Vaccine positive rechallenge

Symptom Text: Case received from a health care professional on 30-JUN-2009. This case was poorly documented. It was reported by a gynecologist that an adult female patient with medical history of neurodermatitis was vaccinated with a third dose of GARDASIL (lot #, injection site and route not reported) on an unspecified date. Subsequently, on unknown date, she experienced aggravation of neurodermatitis. She recovered within approximately three weeks. After first dose and second dose vaccination with GARDASIL the patient experienced aggravation of neurodermatitis too, from which she recovered each time within approximately within three weeks. Follow-up information received on 31-AUG-2009. The reporting form was sent. The patient is 20 years old. Upon additional information (hospitalization) the case was upgraded to serious. In contrast to what was reported initially by phone, aggravation of the neurodermatitis was observed for the first time in February 2008, i.e. shortly after the second dose of GARDASIL (dose 1 on 27-NOV-2007, batch number was NF58550, lot number was 0276U, dose 2 on 28-JAN-2008, batch number was NG00020, lot number was 0277U, given in the upper arm, route not reported). The first dose was well tolerated. Despite ongoing symptoms, the patient received her third dose of GARDASIL (batch number was NH13130, lot number was 1172U) on 07-AUG-2008. In summer/autumn in 2008 the aggravation reached its peak. In September 2008 the patient was hospitalized in a specialized clinic for an unspecified duration. She was treated with cortisone (meanwhile discontinued) and Elidel. The patient has still treatment with acupuncture. Although the reporter crossed the box "recovered" on the reporting form, he mentioned in writing that the symptoms were still ongoing. The case is closed. Other business partner numbers include E2009-0542. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Neurodermatitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356752-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-Jul-2009	13-Jul-2009	0	09-Sep-2009	10-Sep-2009	FR	WAES0908USA00113	10-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0779X	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Blood test, Headache, Vertigo, Vomiting

Symptom Text: Information has been received from a Health Authority (ref # 101634) concerning an 11 year old female patient who on 13-JUL-2009 was vaccinated with the first dose GARDASIL (batch # NJ36070, LOT # 0779X; 0.5 mL, IM, site of administration not reported). Ten minutes after vaccination, the patient presented with asthenia, headache and vomiting. At 30 minutes after events the recovery was not sufficient, the patient was sent to emergency for complementary observation. Continued monitoring of vital sings was performed. Follow up information has been received on 01-SEP-2009. Ten minutes after vaccination, the patient with negative medical history for current chronic diseases presented with one episode of food vomiting with onset of asthenia and intense headache. She was held and monitored for 30 minutes and then sent to the ER because of persistence of the asthenia and onset of vertigo (no coded by HA). She was admitted to the pediatric ward and discharged on 14-JUL-2009 because her general condition had improved. ON 25-AUG-2009 the reporter contacted the patient's mother who confirmed that the child was in good health. The family pediatrician prescribed blood work for anti-EBV antibodies (results not available). The outcome was recovered. At the time of the report, the outcome was not reported. Other business partner numbers include: E200906789. The case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 356754-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Jul-2009	03-Jul-2009	1	09-Sep-2009	10-Sep-2009	FR	WAES0908USA04936	10-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Grand mal convulsion, Reaction to previous exposure to any vaccine

Symptom Text: This case is linked with cases E2009-08226 and E2009-08227. These cases refer to the adverse events occurred after vaccination with first and second doses of GARDASIL. Initial information was received on 25-AUG-2009 from a Health Authority (ES-AGEMED-419915344) concerning an 18 year old female who on 02-JUL-2009 was vaccinated intramuscularly with third 0.5mL dose of GARDASIL (Lot number, batch number and site of administration not reported). It was reported that on 03-JUL-2009, the patient had a tonic-clonic convulsion. Hospital admission (hospital admission and discharge dates have not been reported) and treatment with KEPPRA (dose not reported) were required. The patient recovered on 04-JUL-2009 with sequelae. It was reported that the patient received the first dose of GARDASIL (lot number, batch number and site of administration not reported) by intramuscular route and 48 hours after vaccination, the patient presented with nocturnal disorientation, nausea, concentration difficulty and amnesia. It was reported that the patient was alone in her room at the time, everything was messy. The patient presented neither incontinence nor biting of tongue. The patient received the second dose of GARDASIL (lot number, batch number and site of administration not reported) on 08-JAN-2009. It was reported that the patient presented with a clinical picture of involuntary muscle contractions, predominantly of the face, compatible with myoclonus. Other business partner numbers included: E2009-08225. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **356756-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Feb-2007	07-Jul-2007	130	09-Sep-2009	10-Sep-2009	OK	WAES0909USA00206	04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	1	Unknown	Unknown	
	DTAP	UNKNOWN MANUFACTURER	C2775AA		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2549AA		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Blindness, Diplegia, Dizziness, Headache, Mental disorder, Migraine, Paraesthesia, Paralysis, Tremor, Visual impairment

Symptom Text: Information has been received from a physician concerning a 17 year old female who was vaccinated with a dose of GARDASIL. Two years ago, the patient experienced headaches, paralysis, tremors which prevented her from participating in gymnastics. Therapy with GARDASIL was discontinued. The patient sought unspecified medical attention. At the time of this report the patient had not recovered. The reporting physician considered headaches, paralysis, and tremors to be disabling. Follow up information received on 02-SEP-2009 from a physician indicated that the patient had received only 2 doses of GARDASIL. The third dose of GARDASIL was being held because of the possible link between GARDASIL and the events. The physician also indicated that the patient had been referred to a neurologist. Additional Information was also received from the medical assistant of the patient's primary physician; the medical assistant stated that the patient did not had any medical history or known drugs allergies; the patient received a first dose of GARDASIL (lot # 655618/0186U) on 23-FEB-2007. No other vaccines received on this date. At an office visit on 01-JUN-2007 the patient complained of dizziness and tremors in right hand and right foot. The patient was referred to a neurologist. The patient received a second dose of GARDASIL (lot # 659655/1486U) on 06-MAR-2009. Concomitant vaccination given on 06-MAR-2009 included a dose of DTaP (lot# C2775AA) and a dose of MENACTRA (lot # U2549AA), sites of vaccination not recorded. The patient was not seen since 06-MAR-2008. Additional information has been requested. 12/29/09 Neurological consult received for DOS 06/17/07. Pt c/o nonspecific visual problems and loss of complete vision. Pt was seen by ophthalmologist and diagnosed with migraine. Pt c/o bitemporal headache, tremors in legs, feeling of "pins and needles" in legs, feeling of paralysis, however Pt able to move legs. Neuro exam: wnl. Physician opinion was that Pt's symptoms were likely a psychological/emotional process. Pt r/o Lym

Other Meds:

Lab Data: DX studies: Head CT and EEG: normal.

History: PMH: Hip fracture, L hand fracture; Allergies: NKDA

Prex Illness:

Prex Vax Illns:

Vaers Id: 356757-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	25-Feb-2008	Unknown		09-Sep-2009	10-Sep-2009	--	WAES0909USA00318	12-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	2	Gluteous maxima	Intramuscular	HPV4

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Condition aggravated, Convulsion, Demyelination, Dizziness, Drug administered at inappropriate site, Fatigue, Headache, Hypertension, Hypoaesthesia, Loss of consciousness, Lumbar puncture, Migraine, Nausea, Oral contraception, Paraesthesia, Syncope, Vision blurred, Visual impairment, Vitamin B12 deficiency, Weight decreased

Symptom Text: Information has been received from a health professional concerning a 28 year old female who on 28-AUG-2007 was vaccinated with the first dose of GARDASIL (lot# 658558/1061U) into her left buttocks. Not long after first dose, migraine headache started. On 25-OCT-2007, the patient was vaccinated with the second dose of GARDASIL (lot# 654539/0742U) into her left gluteus and on 25-FEB-2008, was vaccinated with the third dose of GARDASIL (lot# 655327/1287U) into her left gluteus. Concomitant therapy included ALESSE. On 01-MAY-2009, the patient passed out and was hospitalized, a spinal tap was performed. The patient had migraine headache started not long after the first injection. The patient was seeing a neurologist. A MRI performed showed abnormal results. The patient developed demyelination in brain. Questionable Lupus. Upon internal review, questionable lupus was determined to be an other important medical event. Additional information has been requested. 9/16/09 Received vaccine & GYN medical records. Records reveal patient experienced wt loss & fatigue. On 5/1 had seizure, hospitalized & neuro eval done. 10/6/09 Neurological consult received service dates 5/1/09 to 5/21/09. Assessment: Migraine Presented with c/o severe bifrontal headache and episode of syncope. Transient loss of consciousness. Episodes of weakness associated with headaches, visual disturbance, migraine headaches for past year associated with use of oral contraceptives. ```ED, hospital records received 12/16/09. Service dates 5/1/09 to 5/4/09. Assessment: Hospital DX: possible MS, migraine HA, HTN, B12 deficiency, migraines w/OCP. ER dx: Syncope, EKG changes, possible MS exacerbation. Patient c/o headache and dizziness. Nausea, migraine, blurred vision, decreased vision at night. Numbness, tingling, in fingers.

Other Meds: ALESSE

Lab Data: magnetic resonance, 05/01/09, abnormal. LABS and DIAGNOSTICS: CT Brain - Abnormal. MRI Brain - Abnormal. Blood Glucose 94-183 mg/dl (H). CK 112 SI (H). ANA (+).

History: Unknown 9/16/09 Received medical records w/PMH: Allergy: PCN. PMH: Sinus infection, migraine.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356778-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	25-Aug-2009	26-Aug-2009	1	09-Sep-2009	21-Sep-2009	NC		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3011AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	UF486AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site swelling, Pyrexia, Vomiting

Symptom Text: - Fever x 2-3 days (102.0). - Alternate TYLENOL/MOTRIN. - Swelling to injection site. - Push fluids. -Headache x 2 days. - Vomiting x 1-2 days.

Other Meds:

Lab Data: None

History: None indicated

Prex Illness: None indicated

Prex Vax Illns:

Vaers Id: **356790-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Sep-2009	03-Sep-2009	1	09-Sep-2009	21-Sep-2009	MN		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3047AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0249Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Flushing, Immediate post-injection reaction, Laboratory test normal, Nausea, Orthostatic hypotension, Syncope

Symptom Text: Postural Syncope immediately following vaccine. Recurred again within 24 hrs. Flushed, nausea, dizzy when standing with orthostatic BP changes. No rash, no edema. Labs normal. Given IV fluids with symptom improvement.

Other Meds: OCP-levonorgestrel -EES; DRYSOL prn topical

Lab Data:

History: Dysmenorrhea; hyperhidrosis

Prex Illness: Mild cough illness; menstruating

Prex Vax Illns:

Vaers Id: **356792-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Sep-2009	01-Sep-2009	0	09-Sep-2009	21-Sep-2009	AZ		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB350BA	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2933AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0313Y		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure normal, Dyskinesia, Syncope

Symptom Text: Patient fainted after administering HPV vaccine for about 1-2 mins. Vital sysm. stable. Mom witnessed some arching moves. Blood pressure WNL while she fainted.

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **356794-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Sep-2009	02-Sep-2009	0	09-Sep-2009	21-Sep-2009	PR		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0670Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Patient developed dizziness after administration of GARDASIL (2nd dose).

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Sep-2009	01-Sep-2009	0	09-Sep-2009	21-Sep-2009	CO		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB330CA	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Immediate post-injection reaction, Syncope

Symptom Text: Syncopal episode immediately following vaccine administration. Patient was seated, no fall sustained. Blood pressure dropped to 76/48, recovered to 96/56 in 5 minutes.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Nov-2008	24-Feb-2009	103	09-Sep-2009	21-Sep-2009	CT		23-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB289CB	1	Unknown	Intramuscular	VARCEL
FLU	SANOFI PASTEUR	U2898EA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Physiotherapy, Visual impairment

Symptom Text: Onset of chronic headaches 21/2 month following HPV #2 Diagnostic w/u (-).11/30/2009 PCP records 2-9/2009, ENT consult 7/2009 and Neuro consult records 4/2009. Patient with hx of headaches, dizziness, vision changes with headaches. Neuro consult neg, ENT consult dx'd as tension headaches. Tx PT

Other Meds:

Lab Data: Labs: CBC, Lyme titer, ASO, Anti-Dnase B, LFT's, electrolytes all neg Dx studies: MRI Brain neg

History: PMH: None Allergies: NKDA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356808-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Aug-2009	28-Aug-2009	2	09-Sep-2009	21-Sep-2009	WI		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Chills, Pyrexia, Rash macular, Urticaria

Symptom Text: Received Wed 8/26/09 fever next day. Friday - rash, splotches 3-4" across, worse, chills spreading. Saturday & Sunday - hives upset stomach Saturday.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356810-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Jul-2009	23-Jul-2009	14	09-Sep-2009	21-Sep-2009	FL		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2911AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF460CA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia, Rash, Scar, Varicella

Symptom Text: 2 weeks after administration of Gardisil, patient developed severe chickenpox. 1 week of fever, 3 weeks of rash. Patient still has severe scarring of face.

Other Meds: clindamycin gel, salicylic acid topical, benzoyl peroxide

Lab Data: N/A

History: unknown

Prex Illness: acne, dandruff

Prex Vax Illns:

Vaers Id: **356813-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Sep-2009	05-Sep-2009	0	09-Sep-2009	21-Sep-2009	NY		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB287AB	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Syncope

Symptom Text: Pt fainted at about 3:50pm at the waiting area after blood drawn and vaccination, she felt dizzy then passed out for less than 1 min. Code blue was called, pt was attended immediately by nursing staff and provider, she was awake by the time provider arrived. Pt was transferred to Rm 9 for close observation, continuring monitor of vital signs. Initial accessment by provider was normal, pt was observed for 30 mins with normal vital signs. Pt was examined again by provider before discharge, normal exam. Explained to mom that the fainting might be dued to blood drawn or vaccination. Possible postvaccination reaction to HPV, case is reported for further investigation. Pt should have f/u in 1 week.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356814-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Aug-2009	27-Aug-2009	0	09-Sep-2009	21-Sep-2009	PA		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain, Injection site swelling

Symptom Text: Pain, swelling, lump on arm at injection site.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **356835-1 (S)** **Related reports:** 356835-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Mar-2008	31-Oct-2008	228	09-Sep-2009	14-Sep-2009	FL		06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB1244	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1967U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Anaemia, Anaemia haemolytic autoimmune, Arthralgia, Blood product transfusion, Cough, Evans syndrome, Fatigue, Haemoglobin decreased, Idiopathic thrombocytopenic purpura, Iron deficiency, Joint swelling, Malaise, Microcytic anaemia, Oropharyngeal pain, Platelet count decreased, Pyrexia, Thrombocytopenia

Symptom Text: Evans Syndrome. Autoimmune hemolitic anemia + idiopathic thrombocytopenic purpura. Coombs positive (warm Ab). Hb=6 & plts. 20,000. Differential Dx and W/U. All negative and comrehensive. Incluging viral studies, lupus serologies and Bone marrow aspirate and biopsy. Cause still unknown. Treated with transfusions, IVIG, steroids and "wait and see" aproach. Ultimately given Rytuxan. Currently on 'remission' 9/28/09 Medical records and DC summary received from date of service 11/1/08 to 11/7/08. D/C DX:Evans Syndrome. Presented with: malaise x1month,fatigue, fever, sore throat, joint pain/swelling, cough, night sweats, anemia, thrombocytopenia. Insidious onset of symptomatic microcytic hypochromic hyperproliferative anemia with evidence of iron deficiency. TX: IV IG.

Other Meds: None. At the time of vaccination. Treated with Growth Hormone from age 10-13

Lab Data: CBC's.Coobs test. Bone marrow aspirate and BM biopsy. ANA. Retic count. LDH. Complements. Chest x ray. Serologies for Parvo, CMV, HIV, MONO. Iron studies and Chromosome analysis. 9/28/09 Medical records and DC summary received from date of

History: Short Stature 9/28/09 Medical records and DC summary received from date of service 11/1/08 to 11/7/08 PMH: anemia, menstral irregularities with heavy flow, short stature with growth hormone treatment, Oral contraceptives.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **356835-2 (S)** **Related reports:** 356835-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Mar-2008	31-Oct-2008	228	01-Dec-2009	02-Dec-2009	--	WAES0911USA01073	04-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB1244	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1967U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Anaemia, Anaemia haemolytic autoimmune, Arthralgia, Blood product transfusion, Cough, Evans syndrome, Fatigue, Idiopathic thrombocytopenic purpura, Iron deficiency, Joint swelling, Malaise, Microcytic anaemia, Night sweats, Oropharyngeal pain, Pyrexia, Thrombocytopenia

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 15 year old female with anaemia, menstruation irregular with heavy flow and a history of treating with growth hormone from age 10-13 on 17-MAR-2008 was vaccinated with the third dose of GARDASIL IM (therapy dose, site unknown) (Lot# 660387/1967U). Concomitant therapy included the second dose of HAVRIX (therapy dose, route and site unknown) (Lot# AHAVB1244) and oral hormonal contraceptives (unspecified). On 31-OCT-2008 the patient experienced anaemia, anaemia haemolytic autoimmune, arthralgia, blood product transfusion, cough, EVANS syndrome, fatigue, haemoglobin decreased, idiopathic thrombocytopenic purpura, iron deficiency, joint swelling, malaise, microcytic anaemia, oropharyngeal pain, platelet count decreased, pyrexia and thrombocytopenia and was hospitalized. These events were considered to be immediately life-threatening. Coombs test was positive (warm Ab) and haemoglobin=6, platelet=20,000. All tests were negative and comprehensive including bone marrow aspirate and BM biopsy, ANA, reticulocyte count, LDH (Lactate dehydrogenase), complements, chest x ray, serologies for Parvo, CMV, HIV, MONO, iron studies and chromosome analysis. Cause was still unknown. The patient was treated with transfusions, IVIG (intravenous immune globulin), steroids and "wait and see" approach. Ultimately the patient was given RITUXAN. The patient was recently on "remission". On 29-SEP-2009 medical records and diagnoses summary received from date of service 01-NOV-2008 to 07-NOV-2008. The diagnosis was EVANS Syndrome, presented with malaise for one month, fatigue, fever, sore throat, joint pain/swelling, cough, night sweats, anemia, thrombocytopenia, Insidious onset of symptomatic microcytic hypochromic hyperproliferative anemia with evidence of iron deficiency. The treatment was IVIG. The original reporting source was not provided. The VAERS ID # is 356835. A standard lot check investigation was p

Other Meds: hormonal contraceptives

Lab Data: Diagnostic laboratory, Coombs positive (warm Ab); Bone marrow biopsy, bone marrow aspirate biopsy: negative; Diagnostic laboratory, Serologies for Parvo, CMV, HIV, Mono,: negative; Diagnostic laboratory, Iron Studies: negative; Chest x-ray,

History: Hormone therapy

Prex Illness: Anaemia; Menstruation irregular; Menstrual flow excessive

Prex Vax Illns:

Vaers Id: **356846-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Mar-2008	03-May-2008	51	09-Sep-2009	21-Sep-2009	NJ		30-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Anxiety, Arthralgia, Depressed mood, Diarrhoea, Fatigue, Joint range of motion decreased, Joint stiffness, Juvenile arthritis, Lip swelling, Localised infection, Musculoskeletal pain, Musculoskeletal stiffness, Nasal discomfort, Oedema peripheral, Pain, Pain in extremity, Sinusitis, Viral infection

Symptom Text: Diagnosed w/ juvenile rheumatoid arthritis 1/09. Symptoms have been progressive since 2007. Also has asthma, scoliosis and migraine HA. 9/25/09 Medical records/ER visits received DOS 3/11/02 to 06/20/08. Patient presents with infection behind (R) leg. Fatigue. 9/27/09 Medical records received DOS 8/22/08 to 9/5/09. Assessment: Juvenile Idiopathic Arthritis of Polyarticular Subtype / Arthritis Secondary to Bowel Disease. Finger pain and swelling. Loose stools, achiness, knees weak. Generalized pain. Morning pain, stiffness in back, toes, fingers. Shoulder pain. Stomach pain after eating. Nose sore, anxious and sad. Sacroiliac joint pain. Decrease in lumbar flexion. Sinusitis. Viral illness. Lips swelled.

Other Meds:

Lab Data: LABS and DIAGNOSTICS: Rheumatoid Factor 28 (+). Anti-Saccharomyces Cerevisiae Antibody (ASCA) (+). X-ray Hand - Abnormal. PPD (-). CHEM - Glucose 60 mg/dL (L).

History: Pistachio; reaction to valium. Received 2 doses Hep A vaccine recalled for poss lack of potency. Scoliosis, back pain. Scoliosis brace. Thigh, calf pain. Numbness tingling right foot, insomnia. Sacroiliac joint syndrome. Adverse reaction to Valium. Eye rolling and facial twitching. Myoclonic jerking, anxiety, hallucinations, headaches. Panic attacks. Asthma. Vertigo. Injured should

Prex Illness: Asthma; Scoliosis; Migraine HA

Prex Vax Illns:

Vaers Id: **356859-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Sep-2009	04-Sep-2009	1	09-Sep-2009	21-Sep-2009	PA		15-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Numbness and paresthesias in arm and leg on same side of site of injection.12/2/2009 PCP note from 9/4/2009 patint c/o's numbness and tingling in LUE and LLE. no tx noted. Neuro exam did show decreased senastion in these areas. Sx starting to resolve 9/23/2009.

Other Meds: None

Lab Data: No labs or dx studies.

History: Amoxil; Nuts PMH: None Allergies: Amoxicillin, Nuts

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356901-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Aug-2009	31-Aug-2009	0	10-Sep-2009	11-Sep-2009	LA	WAES0909USA00557	11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Tonic convulsion

Symptom Text: Information has been received from a physician concerning an approximately 14 year old female who on 31-AUG-2009 was vaccinated intramuscularly with her first 0.5mL dose of GARDASIL (lot number not reported) . On 31-AUG-2009, after getting the vaccine, the patient "had a syncope and then tonic seizure movements". The patient recovered from syncope and tonic seizure movement on 31-AUG-2009. The patient sought unspecified medical attention. Upon internal review, tonic seizure movement was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **356904-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		10-Sep-2009	11-Sep-2009	FR	WAES0909USA00317	11-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received from a professor, concerning a female who was vaccinated with a dose of GARDASIL. The professor reported that she received a call from a pediatrician, who had seen a baby (ID # 40165), with tracheo-oesophageal fistula. The mother had GARDASIL in early pregnancy. The outcome of the event was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **356915-1** **Related reports:** 356915-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Aug-2008	01-Feb-2009	180	10-Sep-2009	13-Oct-2009	IA		21-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Left arm	Intramuscular	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Rhinitis allergic, Sinusitis

Symptom Text: Severe headache and dizziness after Gardasil Shot! 9/29/09 Medical records received from dates of service 2/2/09 to 8/24/09 PCP, Allergist, ENT, Neurologist. Patient seen by PCP 2/2/09 DX:sinusitis. Presenting with HA. 3/9/09 and 3/18/09 visits no change and C/O HA. 3/24/09 Allergist consult, normal findings. 4/05/09 Neurologist consult DX: tension HA or mixed migraine HA cannot be ruled out suggest to see a specialist for TMJ for clicking in jaw. 4/20/09 and 4/30/09 PCP visit DX:allergic Rhinitis. 5/6/09 ENT consult DX: reccurent sinusitis.

Other Meds:

Lab Data: Bloodtests, CT, MRI, EEG, ENT-Doctor twice, x-rays. All these tests were done between April and May 2009. 9/29/09 Medical records received from dates of service 2/2/09 to 8/24/09 Diagnostics/ Labs: CT face-mucosal thickening within the inf

History: None 9/29/09 Medical records received from dates of service 2/2/09 to 8/24/09 PMH: HA, sinusitis, allergic rhinitis.

Prex Illness:

Prex Vax Illns:

Vaers Id: **356924-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	09-Sep-2009	09-Sep-2009	0	10-Sep-2009	21-Sep-2009	MD		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0243U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Heart rate normal, Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Immediately after receiving Gardasil#3 injection, patient fainted, loosing consciousness for approximately 30 seconds. Easily revived with changing of position & cool compress.BP 100/60 Pulse 70. Pt did not injure self.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 356928-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Jul-2007	29-Sep-2007	81	10-Sep-2009	21-Sep-2009	MO		17-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0447U	1	Unknown	Unknown	
MEN	SANOFI PASTEUR	U197AB	0	Unknown	Unknown	
HPV4	MERCK & CO. INC.	0522U	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB149AA	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Breast pain, Cough, Decreased activity, Decreased appetite, Dysphagia, Headache, Hypoaesthesia, Initial insomnia, Limb deformity, Loss of consciousness, Lymph node pain, Lymphadenopathy, Nasal congestion, Pain in extremity, Paraesthesia, Pharyngitis streptococcal, Rhinorrhoea, Syncope, Tonsillar disorder

Symptom Text: My daughter has passed out TWICE since receiving these injections and experiences increased headaches while the finishing up the series. She has no previous history of passing out and has always been the picture of health. We are very concerned over the long term effects of Gardisil and want the consequences of her receiving these shots documented with both the FDA and her PCP office. Thank you. 9/15/09 PCP medical records received DOS 7/10/07 to 8/24/09. Assessment: Acute strep pharyngitis. Mother says child fainted after first HPV vaccine but did fine with 2nd and 3rd doses. Presents with sore throat, decreased appetite, decreased activity, cough. Tonsils +3 with exudate, mild erythma oropharynx, tender enlargement of anterior cervical nodes. Acute pharyngitis. Headache. Difficulty swallowing, problems falling asleep, nasal congestion/discharge, abdominal pain. Left forearm deformed, tender, numbness, tingling. Left breast tender.

Other Meds: None

Lab Data: 9/15/09 PCP medical records received DOS 7/10/07 to 8/24/09. LABS and DIAGNOSTICS: Rapid Strep (+). Mono (-).

History: None. 9/15/09 PCP medical records received DOS 7/10/07 to 8/24/09. Allergy Sulfa Drugs. Broken left arm. Concussion.

Prex Illness: No. 9/15/09 PCP medical records received DOS 7/10/07 to 8/24/09. Prior to vaccination on 7/10/09 patient c/o painful ankle and p

Prex Vax Illns: Fainting~HPV (Gardasil)~2~13.00~Patient

Vaers Id: **356938-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	21-Jul-2008	12-Sep-2008	53	10-Sep-2009	11-Sep-2009	OK		29-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	17400	2	Left arm	Intramuscular	HPV4

Seriousness: DIED, SERIOUS

MedDRA PT Arrhythmia, Biopsy heart abnormal, Bronchitis, Chest pain, Chills, Death, Dizziness, Dyspnoea, Fatigue, Feeling cold, Headache, Muscle spasms, Nausea, Oropharyngeal pain, Pain, Petechiae, Productive cough, Pulmonary congestion, Pulmonary oedema, Pyrexia, Sputum discoloured, Sternal fracture

Symptom Text: Headache, Nausea, dizziness, chilling, tiredness, shortness of breath, complained of chest plain, severe cramps. 9/14/09 Received vaccine & PCP medical records which reveal patient seen 12/5/07 & 2/27/08 with sore throat, fever, chills, fatigue, body aches, productive cough w/yellow sputum & HA. Dx both times w/acute bronchitis & tx w/antibiotics & cough syrup. 9/25/09 Autopsy report received DOD 09/12/2008. Acute Cardiac Arrhythmia of Unknown Etiology. Addtional information abstracted: Heart with focal microscopic ischemic changes, pulmonary congestion and edema. Rare petechiae: conjunctival, periorbital and laryngeal. Resuscitation related sternal fracture.

Other Meds: Yaz until 3/17/08. Femcon beginning 3/17/08. Anaprox as needed.

Lab Data: None. I do have copies of all medical history from 01/08/2004 to the time of her death that I can provide if needed. The Medical Examiners office will have tissue samples until 4/2010.

History: None

Prex Illness: None

Prex Vax Illns: None~ ()~~0~Patient

Vaers Id: **356939-1 (S)** **Related reports:** 356939-2; 356939-3; 356939-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-May-2009	04-Jun-2009	8	10-Sep-2009	15-Sep-2009	LA		31-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2869AA		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C3068AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0652X		Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abasia, Acute disseminated encephalomyelitis, Asthenia, Autonomic nervous system imbalance, Clonus, Convulsion, Coordination abnormal, Dyspnoea, Encephalomyelitis, Fatigue, Gait disturbance, Headache, Hyperreflexia, Lethargy, Mental status changes, Muscle twitching, Neck pain, Pain in extremity, Palpitations, Pyrexia, Tachycardia, Tremor, Urinary tract infection

Symptom Text: Mental status changes starting 7 days after immunization with fever, headache, lethargy, inability to walk, discoordination, signs of autonomic instability (BP/pulse). Two events of brief seizure with mouth pulling to the left separated by 30 minutes occurring on one day about 1 month following onset of symptoms. Fatigue, intermittent tachycardia, left-sided headache and general weakness have persisted, although improved over the past 3 months. She has diffuse, symmetric hyperreflexia in all extremities with 1-beat clonus of the right ankle. Diagnosis of ADEM was made. No treatment given. 12/23/2009 Clinic note received for DOS 11/18/2009. DX: Post Vaccine ADEEM Patient presented complaint of tachycardia lasting 3 to 4 days, pain in leg, episode of right hand shaking for a few minutes, episode of rapid trembling, shortness of breath and increased headache and fatigue. Assessment: No evidence of recurrence of demyelinating lesion, re-current symptoms are residual from first attack. 12/23/2009 Neurology consult, clinic note and MRI report received for DOS 07/14/2009-11/18/2009. DX: ADEM One week after receiving Gardasil vaccine, patient developed high fever, tachycardia and unsteady gait. Patient was hospitalized (2 days) for headache and tachycardia and was treated with antibiotics. Due to persistent fatigue, patient was re-admitted and diagnostic tests were performed. All symptoms improved. Patient still has fatigue and notes twitching on arms, legs and face. Gait has returned to normal. 01/06/2010 Hospital H&P, consults and diagnostic tests received for DOS 07/13/09- 07/14/09 and laboratory tests received for DOS 06/05/09. DX: Lethargy, Headache, Weakness. Poss. Acute Demyelinating Encephalomyelitis. Patient c/o increasing weakness, pressure in the head when moving, passed out two days earlier, headach. Neurologic examinaton noted hyperreflexia with sustained clonus. ```records received 01/11/2010. ER record for DOS 06/04/09. DX: tachycardia, neck pain, UTI Patient presents with c/o palpi

Other Meds:

Lab Data: MRI of head and spine +/- contrast with small areas of intensity. LP with CSF normal, including evaluation for oligoclonal bands negative. 12/23/2009 Diagnostics: WBC-Elevated, Blood cultures-Negative, Lumbar puncture-Negative, MRI of c

History: 12/23/2009 PMH: Eczema, Allergy to PanMist DM Syrp. PMH: pneumonia, chronic sinusitis, chicken pox. ```MR received 1/25/10PMH: adverse reaction to influenza vaccine, pneumonia, sinusitis, allergic rhinitis.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356939-2 (S)** **Related reports:** 356939-1; 356939-3; 356939-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-May-2009	04-Jun-2009	8	16-Sep-2009	21-Sep-2009	LA		06-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2869AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3068AA	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Asthenia, Body temperature increased, Chills, Convulsion, Headache, Hyperreflexia, Lethargy, Tachycardia

Symptom Text: Temp 104 - tachycardia - headache - generalized weakness. ER visit. Chills - lethargic, seizure hyperreflexia x 4. Admit 6-5-08 and 7-13-09. Dx ADEM.

Other Meds: None

Lab Data: EKG; labs; CT Brain/sinus; MRI Brain/Neck; Spinal Tap

History: PANMIST DM (hyper - nervous)

Prex Illness:

Prex Vax Illns:

Vaers Id: **356939-3 (S)** **Related reports:** 356939-1; 356939-2; 356939-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-May-2009	04-Jun-2009	8	02-Dec-2009	03-Dec-2009	--	WAES0911USA01076	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3068AA	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2869AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abasia, Acute disseminated encephalomyelitis, Asthenia, Autonomic nervous system imbalance, Chills, Clonus, Convulsion, Coordination abnormal, Dyskinesia, Fatigue, Headache, Hemicephalalgia, Hyperreflexia, Lethargy, Mental status changes, Pyrexia, Tachycardia

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 17 year old female with PANMIST DM allergy and with no known medical history was vaccinated with a first dose of GARDASIL vaccine (lot# 661766/0652X) in the right arm (route not reported) on 27-May-2009. Concomitant vaccinations included a first dose of ADACEL (lot# reported as C3068AA) and a first dose of MENACTRA (lot# reported as U2869AA). On 04-Jun-2009, the patient experienced acute disseminated encephalomyelitis, abasia, asthenia, autonomic nervous system imbalance, clonus, convulsion, coordination abnormal, fatigue, headache, hyperreflexia, lethargy, mental status changes, pyrexia, tachycardia, body temperature increased and chills. Seven days after immunization, the patient started mental status changes with fever (104), headache, lethargy, inability to walk, discoordination, signs of autonomic instability. The patient went to emergency room. Two events of brief seizure with mouth pulling to the left separated by 30 minutes occurring on one day about 1 mouth following onset of symptoms. Fatigue, intermittent tachycardia, left-sided headache and general weakness have persisted, although improved over the past 3 months. She was diffuse, symmetric hyperreflexia in all extremities with 1 beat clonus of the right ankle. Diagnosis of ADEM was made. No treatment was given. The listing indicated that one or more of the events required hospitalization (05-JUN-2009 and 13-JUL-2009) and was considered to be immediately life-threatening. The originally reporting source was not provided. The VAERS ID# is 356939. No further information is available. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released.

Other Meds:

Lab Data: Spinal tap, CSF normal, including evaluation for oligoclonal bands negative; Magnetic resonance, head and spine +/- contrast with small areas of intensity; Body temp, 104

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **356939-4 (S)** **Related reports:** 356939-1; 356939-2; 356939-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-May-2009	01-May-2009	0	16-Dec-2009	17-Dec-2009	--		07-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Ataxia, Fatigue, Headache, Pyrexia, Tachycardia

Symptom Text: This 18 year old female received the GARDASIL vaccine and 2 weeks later developed acute disseminated encephalomyelitis. Her initial symptoms were fever tachycardia and headache followed by ataxia. She was discharged and had a recurrence of her symptoms a month later which resolved over the following weeks. She has been left with persistent fatigue and intermittent tachycardia.

Other Meds: None

Lab Data: She had a normal lumbar puncture and an abnormal MRI with two periventricular white matter lesions.

History: Allergies PanMist SM SYRP. Active Problems Normal Routine History And Physical Adult -V70.0 - PMH Eczema -692.9. Family Hx No multiple sclerosis No stroke syndrome No paraplegia of unknown etiology No autoimmune disease. Personal Hx Behavioral history: Not smoking. Alcohol: Not using alcohol. Drug use: Not using drugs. Marital History - Single.

Prex Illness:

Prex Vax Illns:

Vaers Id: **356950-1 (S)** **Related reports:** 356950-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Oct-2006	01-Dec-2006	52	10-Sep-2009	15-Sep-2009	ND		21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0955F	1	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain lower, Abdominal pain upper, Alopecia, Anxiety, Bowel movement irregularity, Candidiasis, Cervical dysplasia, Colitis, Constipation, Cystitis, Depression, Diarrhoea, Disturbance in attention, Dizziness, Dyspepsia, Dysplastic naevus syndrome, Dysuria, Fatigue, Feeling abnormal, Fungal infection, Gastric disorder, Gastrooesophageal reflux disease, Headache, Irritable bowel syndrome, Joint injury, Melanocytic naevus, Memory impairment, Menstruation irregular, Micturition urgency, Mucous stools, Myalgia, Oropharyngeal pain, Pelvic pain, Pollakiuria, Premenstrual syndrome, Sinusitis, Systemic candida, Urinary tract infection, Vision blurred

Symptom Text: Symptoms began with hair loss two months after first shot, progressed to stomach problems, indigestion, bloating, menstrual irregularities, PMS Symtoms very bad, yeast infection, bladder infection, extreme fatigue, extreme headaches, muscle aches, foggy vision, foggy memory, inability to concentrate, depression, anxiety. We are currently treating her for Systemic Candidias. 9/18/09 PCP medical records received DOS 10/2/06 to 6/27/08. Assessment: Cystitis. Irritable bowel syndrome alternating type. GERD. Patient presents with urinary urgency, dysuria, and frequency. Hypogastric tenderness. Nevus on shoulder. Dysplastic Nevus. Multiple benign nevi. Sinus infection, stomach ache, constipation, feeling run down, sore throat. UTI. Diarrhea. Ankle injury. Bloating. Dizziness, 'spacy', hair loss. Mucous in stool. Pelvic pain. LGSIL. Abnormal bowel movement pattern. Inflammation of colon.

Other Meds: None. 9/18/09 PCP medical records received DOS 10/2/06 to 6/27/08. Ortho Tri-Cyclen

Lab Data: Doctors performed many tests and we came back with no answers. Other than positive results for numerous yeast infections and bladder infections. 9/18/09 PCP medical records received DOS 10/2/06 to 6/27/08. LABS and DIAGNOSTICS: Urinalysis

History: None. 9/18/09 PCP medical records received DOS 10/2/06 to 6/27/08. Septal rhinoplasty with tonsillectomy.

Prex Illness: None. 9/18/09 PCP medical records received DOS 10/2/06 to 6/27/08. Metrorrhagia

Prex Vax Illns:

Vaers Id: **356950-2 (S)** **Related reports:** 356950-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Oct-2006	01-Dec-2006	52	04-Dec-2009	07-Dec-2009	--	WAES0911USA01078	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0955F	1	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain lower, Abdominal pain upper, Alopecia, Anxiety, Bowel movement irregularity, Candidiasis, Cervical dysplasia, Colitis, Constipation, Cystitis, Depression, Diarrhoea, Disturbance in attention, Dizziness, Dyspepsia, Dysplastic naevus syndrome, Dysuria, Fatigue, Feeling abnormal, Fungal infection, Gastric disorder, Gastrooesophageal reflux disease, Headache, Irritable bowel syndrome, Joint injury, Melanocytic naevus, Memory impairment, Menstruation irregular, Micturition urgency, Mucous stools, Myalgia, Oropharyngeal pain, Pelvic pain, Pollakiuria, Premenstrual syndrome, Sinusitis, Tenderness, Urinary tract infection, Visual impairment

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. An 18 year old female with metrorrhagia and a history of septal rhinoplasty with tonsillectomy was vaccinated with a second dose of GARDASIL (lot# 653978/0955F) IM in the left arm on 10-OCT-2006. Concomitant therapy included ORTHO TRI-CYCLEN. Symptoms began with hair loss two months after first shot, from 01-DEC-2006, progressed to stomach problems, indigestion, bloating, menstrual irregularities. PMS symptoms very bad, yeast infection, bladder infection, extreme fatigue, extreme headaches, muscle aches, foggy vision, foggy memory, inability to concentrate, depression, anxiety. She was treated for systemic candidias. PCP medical records received assessment: cystitis, irritable bowel syndrome alternating type and GERD. Patient presented with urinary urgency, dysuria and frequency, hypogastric tenderness, nevus on shoulder, dysplastic nevus, multiple benign nevi, sinus infection, stomach ache, constipation, feeling run down, sore throat, UTI, diarrhea, ankle injury, bloating, dizziness, "spacy", hair loss, mucous in stool, pelvic pain, LGSIL, abnormal bowel movement pattern and inflammation of colon. The listing indicated that one or more of the events was considered to be immediately life-threatening. The originally reporting source was not provided. The VAERS ID# is 356950. No further information is available. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Agency and was released.

Other Meds: Unknown

Lab Data: diagnostic laboratory - numerous yeast infection and bladder infection

History: Rhinoplasty; Tonsillectomy

Prex Illness: Metrorrhagia

Prex Vax Illns:

Vaers Id: 356962-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Sep-2009	10-Sep-2009	2	10-Sep-2009	15-Oct-2009	AZ		15-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y9	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	V3021AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Erythema, Headache, Malaise, Neck pain, Pain in extremity, Rash

Symptom Text: Severe pain 2 days after injection- neck & left side of upper body down arm into elbow, symptoms/pain are continuing to increase & travel down arm. Face showing redness/rash on cheeks & chin. Day of vaccine: headache, sick, slept.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: Sever fever and seisure~Measles + Mumps + Rubella (MMR II)~1~1.50~Patient

Vaers Id: 356979-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Aug-2009	01-Sep-2009	1	11-Sep-2009	14-Sep-2009	FR	WAES0909USA00919	14-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Guillain-Barre syndrome, Hyporeflexia, Muscle contracture, Muscle spasms, Muscular weakness, Nausea, No reaction on previous exposure to drug, Paraesthesia, Pelvic pain

Symptom Text: Case received from a physician on 04-SEP-2009: A 17 year old female patient had received the second dose of GARDASIL (Lot number not reported) in her left arm, on 31-AUG-2009. The following day after vaccination i.e. on 01-SEP-2009, the patient experienced on both arms, especially on right arm, paresthesia with the sensation of muscle cramps, decreasing of muscular strength: the patient noticed a latent period to perform an action with her arm. Nothing was observed at the site of injection. The following days, the patient experienced lumbar contractures, nausea and abdominal pain, but pelvic; the patient was in the middle of her menstrual cycle and was under contraception. These events were predominantly nocturnal. Consultations on 07-SEP-2009 found diffuse paresthesia of right arm, significant decreased of right osteotendinous reflexes. It was specified that at the beginning of the symptoms, the patient experienced paresthesia at right foot which quickly resolved. Corrective treatment with paracetamol, VOGALENE, Phloroglucinol Hydrate; SPASFON were given. Neurology consultation was planned at the time of the report (in the afternoon), for a suspect Guillain-Barre syndrome but the time to onset seemed very short. To be noted that the patient had not experienced fever or infectious signs recently, and that she was taken oral contraception. On 03-JUN-2009, she had received the first dose of GARDASIL without problems. Guillain-Barre syndrome, nausea and abdominal pain were considered to be other important medical events. Other business partner numbers include E2009-08410.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356980-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Apr-2008	Unknown		11-Sep-2009	14-Sep-2009	SC	WAES0909USA00783	14-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse for GARDASIL, a pregnancy registry product, concerning an 18 year old female patient who in April 2008 was vaccinated with the second dose of GARDASIL. After receiving her second dose the patient became pregnant and miscarried. the last menstruation period was unspecified. She reported this to office after the event and they followed up with a Pap smear which came back normal. No lot number provided. At the time of report the patient's status was unknown. Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, abnormal

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 356981-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Dec-2008	01-May-2009	130	11-Sep-2009	14-Sep-2009	MI	WAES0909USA00762	04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	1	Left arm	Intramuscular	HPV4 MNQ

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Aspiration pleural cavity, Breath sounds abnormal, Chest pain, Cough, Deep vein thrombosis, Dyspnoea, Iron deficiency anaemia, Lobar pneumonia, Pleural effusion, Pulmonary embolism, Renal failure acute, Respiratory distress, Respiratory rate increased, Tachycardia, Thrombosis, Viral infection

Symptom Text: Information has been received from a physician concerning a 19 year old female patient with no pertinent medical history and no known drug allergy who in August 2008 was vaccinated with the first dose of GARDASIL. In January or February 2009 the patient was vaccinated with the second dose of GARDASIL. Concomitant therapy included birth control pills (unspecified) for years. In May 2009, the patient developed a blood clot in the leg that resulted in a pulmonary embolism. She was hospitalized for several days. She was currently considered to be recovered but still taking COUMADIN. Her initial and second dose of GARDASIL were given at another office so no administration information available. The physician could not give any other details and said he was not consulted on this case. He learned of the incident through the patient's mother. He did not have the name of the physician who administered the GARDASIL, and did not know the name of the hematologist who followed the patient. The physician did not offer to contact the patient's mother to gain this information. The health care professional contacted during telephone follow-up could not supply the following information: dates of vaccination/therapy, lot numbers, healthcare provider name and contact information. Additional information has been requested. 9/18/09 Hospital records received DOS 5/27/09 to 6/4/09. Assessment: Right lower lobe pulmonary embolism acute. Left leg DVT. Iron deficiency anemia. Pleural effusion. Viral syndrome 3 weeks prior followed by difficulty breathing. Patient now c/o increasing chest pain and shortness of breath last 7 days. Could not breath. Respiratory distress. Nonproductive cough. Decreased breath sounds right side. Anxiety. Tachycardia. Increased respiratory rate. Thoracocentesis. Acute mild renal failure. Right lower lobe pneumonia. ICD-9 Codes: 415.19 Oth Pulm embolism/Infrac, 486 Pneumonia Organism NOS, 453.41 DVT Proximal Leg, 511.9 Pleural Effusion NOS, E932.2 ADV EFF Ovarian Hormones, 280.9 Iron Defic Anemia NOS, 5

Other Meds: hormonal contraceptives

Lab Data: Unknown. 9/18/09 Hospital records received DOS 5/27/09 to 6/4/09. LABS and DIAGNOSTICS: CT - Abnormal. Venous Doppler lower extremity - Abnormal. EKG - NSR. Chest X-ray - Abnormal. Iron 43 ug/dL (L) Iron saturation 13% (L) Ferritin 448 ng/m

History: 9/18/09 Hospital records received DOS 5/27/09 to 6/4/09. Birth Control Pills. Anemia.

Prex Illness:

Prex Vax Illns:

Vaers Id: **356982-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-May-2009	03-Aug-2009	87	11-Sep-2009	14-Sep-2009	UT	WAES0909USA00753	01-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2665AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0928U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Grand mal convulsion, Incontinence, Loss of consciousness, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning an 11 year old female who was vaccinated with the second dose of GARDASIL (dose, route, and lot not reported) one month ago (on approximately 03-AUG-2009). There was no other concomitant immunization medication. The patient experienced an an adverse event post vaccination with GARDASIL. 40 minutes post vaccination the patient had a "tonic clonic seizure event" in the car with her parents. The patient was taken to the doctor office for follow up. The patient recovered. It was noted that the patient was nervous about vaccinations and she had passed out after the first dose of GARDASIL. Upon internal review, "tonic clonic seizure event" was determined to be an other important medical event. Additional information has been requested. 9/29/2009 Received PCP medical records of 5/8/09-8/13/09 which reveal patient in usual state of health on 5/8/09. RTC on 8/13/09 w/report of 2nd episode of LOC & seizure w/jerking movements of arms/legs & incontinence lasting approx 1 min after receiving 2nd HPV. No further medical treatment was sought.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown 9/29/09 Received medical records w/PMH: idiopathic scoliosis. HPV#2 given 8/12/09, lot # 1487U.

Prex Illness:

Prex Vax Illns:

Vaers Id: **356983-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	27-Dec-2008	10-Feb-2009	45	11-Sep-2009	14-Sep-2009	FR	WAES0909KOR00009	14-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain lower, Condition aggravated, Cyst removal, Endometriosis, Ovarian cyst, Surgery

Symptom Text: Information has been received from a physician concerning a 24 year old female with bilateral ovarian cyst who on 27-DEC-2008 was vaccinated with the second dose of GARDASIL. Concomitant therapy included YASMIN. The reporting investigator mentioned that the patient had been diagnosed approximately in 2007 as bilateral ovarian cyst, and watchful waiting had been suggested. On 10-FEB-2009, the patient experienced low abdominal pain, so visited ER. On the same day, pelvic CT was done, and the results was 'interval increased size of septate cystic lesion in both adnexae - Endometriosis, most likely'. The patient was hospitalized to receive cyst removal on 25-FEB-2009, and the surgery was done on 26-FEB-2009. The patient was discharged on 27-FEB-2009. The reporting investigator felt that increased size of bilateral ovary cyst was not related to therapy with GARDASIL. Additional information has been requested.

Other Meds: drospirenone (+) ethinyl estradiol, 20Nov08-24Feb09

Lab Data: computed axial tomography, 10Feb09, interval increased size of septate cystic lesion in both adnexae- Endometriosis, most

History:

Prex Illness: Ovarian cyst

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **356984-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	25-Jul-2007	28-Aug-2009	765	11-Sep-2009	14-Sep-2009	FR	WAES0909USA00600	14-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a 25 year old female who on 25-JUL-2007 was vaccinated with the first dose of GARDASIL. On 25-SEP-2007 was vaccinated with the second dose and on 25-JAN-2008 was vaccinated with the third dose (lot numbers not reported). The physician reported that on 25-JUL-2007 before vaccination, the patient had a Pap smear that was clear and on 25-JUL-2008 six months following the completion of vaccination, another Pap smear that was also clear. On 28-AUG-2009 the patient had a Pap smear grade III. The physician reported that a biopsy and a colposcopy would be done. At the time of reporting the outcome was unknown. Pap smear grade III was considered to be another important medical event by the reporting physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, 25Jul07, clear; cervical smear, 25Jul08, clear; cervical smear, 28Aug09, REVEALED CIN III

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **356985-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	29-Aug-2009	29-Aug-2009	0	11-Sep-2009	14-Sep-2009	--	WAES0909USA00773	14-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a pharmacist concerning a female patient with a history of "aversion" to the needles who was vaccinated with the first dose of GARDASIL "last week". The patient also was vaccinated with PNEUMOVAX 23. Immediately after the vaccination the patient fainted and developed convulsion. The patient also experienced convulsion. The patient was taken to the hospital as a precaution. At the time of report the patient's status was unknown. Upon internal review, convulsion was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Fear of needles

Prex Illness:

Prex Vax Illns:

Vaers Id: **356991-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Jun-2008	01-Sep-2009	435	11-Sep-2009	21-Sep-2009	KY		25-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0181U	2	Right arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Confusional state, Convulsion, Depressed level of consciousness, Dyskinesia, Fall, Fatigue, Feeling abnormal, Feeling hot, Grand mal convulsion, Head injury, Headache, Musculoskeletal stiffness, Neurological examination normal, Postictal state, Sinusitis, Swollen tongue, Tongue biting, Tongue discolouration

Symptom Text: patient recieved Gardasil on 12/19/07, second dose on 2/20/08, and last dose on 6/23/2008. Extremely tired and at times seemed slow to respond.On 6/24/2009, went to family doctor to get menactra for college admission. That night patient had seizure during sleep. Bit tongue severely and had memory loss.Went to doctor, told to watch and wait. On 9/1/2009, patient suffered grand mal seizure at college and was taken to emergency room and evaluated. Sent to see neurologist next day and put on lamictal to control seizures. Following up on Sept 18 2009 with EEG and MRI.No family history at all of seizures and has been diagnosed with sudden onset seizures. 9/15/09 PCP and Neurology consult records received DOS 6/26/09 to 9/2/09. Assessment: Seizure disorder. Patient c/o 'feeling really weird', woke up with discoloration and swelling left side of tongue. Trouble recalling things, took longer to remember things. Felt hot. Tongue bitten. Second seizure. Stiffening, jerking. Collapsed to floor. Taken to ER. Neurological exam WNL. 9/15/09 PCP and Neurology consult records received DOS 6/26/09 to 9/2/09. Assessment: Seizure disorder. Patient c/o 'feeling really weird', woke up with discoloration and swelling left side of tongue. Trouble recalling things, took longer to remember things. Felt hot. Tongue bitten. Second seizure. Stiffening, jerking. Collapsed to floor. Taken to ER. Neurological exam WNL. 9/24/09 ER records received DOS 9/1/09. Assessment: New onset seizure. Seizure occuring just prior to arrival. Head injuries. Post-ictal headache and mild confusion. Sinusitis.

Other Meds:

Lab Data: Still doing tests. Will have mri and eeg. LABS and DIAGNOSTICS: Cranial CAT Scan Unremarkable. Cervical Spine CAT Scan Unremarkable. Blood Studies Unremarkable. 9/24/09 ER records received DOS 9/1/09. LABS and DIAGNOSTICS: Normal EKG

History: none 9/15/09 Received medical records w/Menactra, Lot #U2670AA, given LA on 6/24/2009.

Prex Illness: none, healthy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357021-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		11-Sep-2009	13-Oct-2009	NV		13-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0850Y	2	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered

Symptom Text: 3rd Varicella given accidentally. Previous dose, #1 not properly recorded, discovered previous count 3 given.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357040-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Aug-2009	31-Aug-2009	18	11-Sep-2009	14-Oct-2009	PA		14-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0378Y		Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin lesion, Urticaria

Symptom Text: Patient developed urticaria/lesions following administration of varicella vaccine.

Other Meds: Multivitamin

Lab Data:

History: DEMEROL

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357068-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	11-May-2009	01-Jul-2009	51	12-Sep-2009	22-Sep-2009	IN		18-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Asthma, Body temperature increased, Colitis, Computerised tomogram abnormal, Dizziness, Fatigue, Haematochezia, Headache, Menstruation irregular, Nausea, Proctalgia, Vertigo, Vomiting

Symptom Text: Had dizziness after first shot on 5/11/2009. My daughter had mild dizziness and headaches on and off after shot but the first week of July she had severe dizziness and nausea. Taken to emergency room for treatment. Treated with antibiotic and antivert. 10 days after this visit, taken back to emergency room with 103 degree temp, severe abdominal pain, dizziness, nausea and vomiting. Also had asthma attack that required rescue inhaler. Had not had asthma attack for over 10 years. Treated at ER with IV fluids, IV antibiotics, IV pain medications and IV antiemetics. CT of abdomen showed infection of the colon. Sent home on Flagyl, Cipro, Lortab and Phenergan. Had some blood in stool and rectal pain for 3 weeks after this visit. Continues to have dizziness, nausea and left upper quadrant abdominal pain. Has bleeding between periods and fatigue. Prior to the Gardisil shot, my daughter was healthy and had not been in emergency room for over 5 years. She was scheduled for her second shot on 7/13/2009 and we did not get it. 11/3/2009 records from ED visits 7/2 and 7/11/2009.Dc Dx Vertigo, abdominal pain, Colitis Patient presented on 7/2/2009 with c/o's vertigo and dizziness. Tx'd with antivert, medrol dose pak. On 7/11/2009 patient presented with c/o's nausea, vomiting, fever and LUQ abd pain. Tx: IVF, IV ABX, IV Zofran and Dilaudid. ```2/17/2010 OB records for 9/14/2009 f/up visit patient with c/o's cramps with periods, BCP to be changed to LoEstrin, patient declined 2nd Gardisil vaccination.

Other Meds:

Lab Data: Labs 7/11 CBC, WBC 17.0 high, Chem profile Low Na, high glucose, Urine pregnancy test neg Dx tests: Ct Abd/Pelvis noted ? inflammatory colitis ```2/17/2010 OB records for 9/14/2009 f/up visit

History: Allergies: Metal (dermatitis), antihistamine/decongestant combinations, Medical:S/P perthes L hip, asthma (controlled),seasonal allergies PMH: Asthma Allergies: antihistamine/decongestant mix ```2/17/2010 OB records for 9/14/2009 f/up visit

Prex Illness: None ```2/17/2010 OB records for 9/14/2009 f/up visit

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Sep-2009	11-Sep-2009	1	11-Sep-2009	14-Oct-2009	NY		10-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U3208AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Feeling cold, Syncope, Vaccine positive rechallenge

Symptom Text: Fainting, feeling of coldness and weakness. Same reaction on 02/12/2009 but vaccine was given with other four.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357105-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Sep-2009	09-Sep-2009	0	11-Sep-2009	14-Oct-2009	PA		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	MNQ
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB296AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Nausea, Tinnitus, Vision blurred, Visual impairment

Symptom Text: 10 mins after vaccine admin. pt c/o dizzy --> sat down c/o ears ringing, blurred vision & seeing spots, nauseous & diaphoretic --> lasted approx 10 mins. BP 96/60.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357132-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	17-Sep-2008	20-Oct-2008	33	14-Sep-2009	15-Sep-2009	FL	WAES0811USA02648	15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a 22 year old female consumer with no pertinent medical history or drug reactions or allergies, for the Pregnancy Registry for GARDASIL, who on approximately 17-SEP-2008, "about two months ago", was vaccinated with the second dose of GARDASIL. There was no concomitant medication. On 17-NOV-2008, "today", she did a home pregnancy test and found out that she was pregnant. The LMP was 20-OCT-2008. No adverse event involved. The consumer reported that she had called her physician, but had not seen the physician as of yet. Follow-up information was received from the patient which reported that the pregnancy resulted in miscarriage after two months (on approximately 20-DEC-2008). The patient thought it was due to GARDASIL especially that "she was only 22 year old and already had one child". The patient stated that she never received her third dose. Upon internal review, miscarriage was considered to be other important medical event. The patient also reported that she recently got pregnant again (WAES # 0909USA00978). Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, 11/17/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 10/20/2008)

Prex Vax Illns:

Vaers Id: **357133-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jan-2006	01-Jan-2008	730	14-Sep-2009	15-Sep-2009	NY	WAES0908USA04768	15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Arnold-Chiari malformation, Dizziness, Headache

Symptom Text: Information has been received from a nurse concerning a 20 year old female with no drug allergies and no pertinent medical history who in 2006-2007 had possibly received the entire series of GARDASIL (LOT# not reported). the patient started having headaches in the winter of 2008. The MRI or computed axial tomography of the brain was performed on an unspecified date showing chiari malformations. Unspecified eye studies and a computed axial tomography of brain (CT scan) were also performed with no reported results. The patient had an office and emergency room visit. The patient continues to have persistent headaches. Follow-up information has been received via a telephone call from the nurse concerning the 20 year old female patient. The patient received GARDASIL while away at college several years ago. The nurse reported that the patient experienced chronic headaches for more than 6 months. The nurse also reported that the patient's first MRI was performed in January 2008 and was diagnosed with mild chiari malformations and the rest of the MRI was normal. On 02-AUG-2008 the patient went to the emergency room for headache and dizziness. The patient was admitted. They ruled out meningitides and performed another MRI where they concluded there was no change in the scan. The patient was discharged on 03-AUG-2008 with mild chiari malformations; the patient was under the care of a neurologist and was treated with unspecified medications. The patient was hospitalized. The patient's mother was questioning the relationship between her daughter's chronic headaches and her GARDASIL series; the office did not believe the headache was related to GARDASIL. Additional information is not expected.

Other Meds: None

Lab Data: magnetic resonance, 01/??/08, was diagnosed with mild CHIARI malformations and the rest of the MRI was normal; magnetic resonance, no change in the scan

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357134-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	27-Aug-2009	27-Aug-2009	0	14-Sep-2009	15-Sep-2009	--	WAES0909USA00694	15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse practitioner concerning a 21 year old female with no known drug allergies or pertinent medical history who on 27-AUG-2009 was vaccinated with the first dose of GARDASIL (lot no.663454/0672Y). Concomitant therapy included ORTHO EVRA. On 27-AUG-2009 the patient experienced seizure 30 seconds following vaccination and quickly recovered. In follow up, the nurse practitioner reported there were no laboratory or diagnostic tests performed and no treatment necessary. Upon internal review seizure was considered to be an other important medical event. No further information is available.

Other Meds: ORTHO EVRA

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **357135-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-May-2009	01-May-2009	0	14-Sep-2009	15-Sep-2009	FR	WAES0909USA00796	15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthritis reactive

Symptom Text: This case was initially reported to the Agency by the Health Authority, reference no: 20485001 on 03-SEP-2009. This case concerned a 17 year old female patient. Details of the patient's medical history and concomitant medication had not been reported. In May 2009 (exact date not reported), the patient received a dose of GARDASIL intramuscularly (batch number and site not reported). On an unreported date, two weeks post vaccination, the patient experienced reactive arthritis. The patient received treatment with DICLOFENAC and was then attending rheumatology. The patient had not recovered. Both the reporter and the Agency considered this to be a serious reaction due to disability and incapacity. This case is closed. Other business partner numbers included: E2009-08390. No more information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 357136-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-May-2009	Unknown		14-Sep-2009	15-Sep-2009	FR	WAES0909USA00847	15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1050U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune hepatitis, No reaction on previous exposure to drug, Transaminases increased

Symptom Text: Information has been received from a general practitioner concerning a 17 year old female who on 08-SEP-2008 and 27-JAN-2009 was vaccinated with the first (lot# 1114U, batch# NH10940) and second (lot# 0933U, batch# NH46260) doses of GARDASIL. The patient was well tolerated with the first dose of vaccination of GARDASIL. The patient was vaccinated with a third dose of GARDASIL (lot# 1050U, batch# NH32140) IM into the upper arm on 12-MAY-2009. On an unspecified date the practitioner visited and within the preparation of a dental operation the patient was diagnosed with elevated transaminases. A further blood sample was taken and showed increased values for antinuclear antibodies (ANA) (1:640) and anti-nuclear antibodies. Smooth muscle antibodies (anti-SMA) were positive (1:80). Electrophoresis was marginal pathologic. Virus hepatitis serology was negative. The diagnosis of autoimmune hepatitis was established. At the time of reporting, the patient had not yet recovered. Autoimmune hepatitis was determined to be an other important medical event. Other business partner numbers included: E2009-08391. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, showed increased value for antimuscular antibodies; diagnostic laboratory test, virus hepatitis serology was negative; serum ANA, 1:640, increased value; serum antismooth muscle antibody test, 1:80, positive; ser

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **357137-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Feb-2009	01-Apr-2009	59	14-Sep-2009	15-Sep-2009	FR	WAES0909USA01062	15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cervix carcinoma stage 0

Symptom Text: Case received from a physician specialist on 12-JUN-2009 and transmitted through a self-representative: A 22 year old female patient with no relevant medical history received the second dose of GARDASIL (batch number not reported) via intramuscular route in the arm in February 2009. She had received the first dose in November 2008. A smear test had been performed in October 2007 and was normal. In April 2009, ie two months after vaccination, cervical carcinoma in situ was diagnosed, confirmed by colposcopy and biopsy. She was hospitalized on an unspecified date. At the time of report, the patient was on her way to recover. Follow-up information received on 08-SEP-2009: The patient was operated on and recovered. This is originally reported by a health care professional. Other business partner numbers included E2009-05024.

Other Meds: Unknown

Lab Data: colposcopy, ??Apr09, cervical carcinoma in situ; biopsy, ??Apr09, cervical carcinoma in situ; Pap test, ??Oct07, normal

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357138-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Feb-2009	25-Feb-2009	1	14-Sep-2009	15-Sep-2009	FR	WAES0909CAN00001	15-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0858X	2	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Juvenile arthritis, Pain in extremity

Symptom Text: Information has been received from the parent of a 13 year old female who on 24-FEB-2009 was vaccinated with the third dose of GARDASIL, lot# 0858X, intramuscular in left deltoid. There was no concomitant medication. On 25-FEB-2009, the next morning, the patient's hands and feet hurt. The patient started ADVIL and naproxen. In approximately March 2009 (within 4 weeks), the patient experienced full-on juvenile arthritis, polyarticular. The patient was seen at the hospital. She is now on prednisone and methotrexate. Full-on juvenile arthritis, polyarticular was considered to be disabling. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357153-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	15-Apr-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		05-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was noted at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357154-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	15-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	11304	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357155-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	18-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was noted at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357156-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	22-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 357157-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	22-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		05-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357158-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	22-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1103X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was not stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357159-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	22-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1003Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357160-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 357161-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	16-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: Gardisil vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357162-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Jun-2000	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	11304X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357163-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	15-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1330X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: Gardisil vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357164-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: Gardisil vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357165-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	08-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: Gardisil vaccine was stored at temperature that was out of normal.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357166-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	08-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357167-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of range

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357168-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	05-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357169-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		05-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at a temperature that was out of range.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357170-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	05-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 357171-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	18-May-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: Gardisil vaccine was store at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357172-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	18-Mar-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357173-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	19-May-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		05-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357174-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	19-May-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357175-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-May-2009	Unknown		14-Sep-2009	25-Sep-2009	MO		25-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 357176-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-May-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357177-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	27-May-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: Gardisil vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357178-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	27-May-2007	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357179-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-May-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: Gardisil vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357180-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 357181-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357182-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	02-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357183-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357186-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Sep-2009	10-Sep-2009	2	14-Sep-2009	22-Sep-2009	KS		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Jaundice, Ocular icterus

Symptom Text: Mom reports pt developed jaundice on Thursday am by Aunt who is a nurse. Pt's sclera was visibly jaundiced. That was the only symptom. Mom denies pt having fever, N/V, pain or other problems. Pt was eating and drinking with activity as normal for the pt. 9/18/09 Labs received from pcp. Pt was not seen for office visit. Labs: Total bili 0.72 (WNL). Direct bili 0.14 (WNL). Alk phos 250 (H). ALT 31 (H). AST 11 (WNL).

Other Meds: none

Lab Data: Pt is having a liver panel drawn this am but upon calling mom this am, mom reports pt is less jaundiced and continues to feel and act fine. Labs: Total bili 0.72 (WNL). Direct bili 0.14 (WNL). Alk phos 250 (H). ALT 31 (H). AST 11 (WNL)

History: NKA-none medical conditions reported

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357200-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Sep-2009	03-Sep-2009	1	14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1584X	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1497X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3018AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3246BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abasia, Abdominal pain upper, Headache, Hypoaesthesia, Mobility decreased, Pain in extremity, Paraesthesia

Symptom Text: On 9/4/09@ 1400 client called me and notified me of the following information...9/3/09 @0630 client states woke up with tingling pain in bilateral lower extremities. States was able to attend school but also had tummy ache, head ache but no temp. Denies having taken any other meds to help aleve some of the discomfort. On 9/4/09@0630 client stated when getting out of bed that morning she was unable to walk due to pain in both legs. Client describes pain as feeling like your legs are asleep but they're tingling so bad it hurts to move them. States pain is bilateral lower extremities and nowhere else. Client denies having taken anything for the pain. I was taking the report on 9/4/09 at approx. 2pm and asked if she had taken any meds to help alleviate pain and client denies at this time, but does state that symptoms have subsided. I instructed her to see a pcp at the local walk in clinic immediately to evaluate symptoms. Client voices that she will do so as soon as we hang up. 9/7/09@0815 Phone call made to client to check on progress. Aunt state's she is better and is at school @ this time but will have patient call when she's back from school today. 9/8/09@1600 patient returns call and states that all the s/sx have disappeared. She worked an 8 hour shift on that Saturday 9/5/09 following onset of her s/sx and did fine. Denies having seen a doctor for any follow up care states that she feels fine and didn't feel like she needed further care.

Other Meds: zicam taken 9/6/09

Lab Data: None

History: allergy to peanuts

Prex Illness: Denies

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357201-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	02-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: Gardisil vaccine was stored at at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357202-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	02-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357203-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	02-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357204-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	02-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		05-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357205-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 357206-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	02-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357207-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	03-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: Gardisil vaccine was store at temperature that was out of normal range.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357218-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Jul-2007	10-Sep-2007	69	15-Sep-2009	24-Sep-2009	OR		30-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Autoimmune disorder, Mechanical urticaria, Rash, Rash erythematous, Rash macular, Rash pruritic, Urticaria

Symptom Text: Shortly after vacinnation with Gardasil, patient developed Demographia, an auto-immune disorder for which she takes prescription meds, and has been told this is lifelong condition. 9/21/09 Medical records received DOS 9/10/07 to 11/8/07. Assessment: Dermatographism. Patient c/o itchy red bumpy rash on back, neck, and arms. red blotches and long linear wheals. Urticaria. Breaking out daily with hives. 9/24/09 PCP medical records received DOS 3/30/07 to 2/18/08. Assessment: Hives. Patient presents with itchy spreading rash. Continues breaking out daily in hives.

Other Meds:

Lab Data:

History: 9/21/09 Medical records received DOS 9/10/07 to 11/8/07. Latex allergy.

Prex Illness:

Prex Vax Illns: dermographia~HPV (Gardasil)~~13~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357221-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: GARDASIL vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357222-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	03-Jun-2009	Unknown		14-Sep-2009	24-Sep-2009	MO		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug

Symptom Text: Gardisil vaccine was stored at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357276-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	02-Sep-2009	03-Sep-2009	1	15-Sep-2009	25-Sep-2009	NC	NC09040	23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2926AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336BA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0807Y	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Skin warm

Symptom Text: 9-3-09 Back of Lt arm red, > than golf ball in size, hot to touch & feels swollen inside. Per Dr. Ok to give BENADRYL & cool compress if tender or improved to go the ED or RTC. (9-8-09) spoke with mom & did get worse on 9-4-09 & went to ER. given PREDNISONE. Today 9-8-09 much better.

Other Meds: REGLAN, HYDROXYZINE, PROLOL

Lab Data:

History: Bipolar, manic depression, cleft palate

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Jun-2009	13-Jun-2009	3	15-Sep-2009	25-Sep-2009	KS		25-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0042Y	1	Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B036BA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1497X	1	Right arm	Intramuscular	
HEP	MERCK & CO. INC.	1677X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Erythema, Nausea, Pruritus, Swelling, Urticaria, Varicella, Vomiting

Symptom Text: Approx. 3 days after varicella immunization client and mother reports she had a red, swollen, welted area approx. 4-5 inches that was itchy. 4-5 days after that mother states she got the chicken pox and had nausea, vomiting and diarrhea.

Other Meds:

Lab Data:

History: PCN

Prex Illness: None

Prex Vax Illns:

Vaers Id: 357284-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	29-Feb-2008	29-Feb-2008	0	15-Sep-2009	16-Sep-2009	VA	WAES0908USA04775	16-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Prolonged labour

Symptom Text: Information has been received from a nurse for GARDASIL, a pregnancy Registry Product, concerning a 19 year old female who on 29-FEB-2008 was vaccinated with the third 0.5mL dose of GARDASIL intramuscularly. Concomitant therapy included "Tetanus shot". Subsequently, she became pregnant. On 11-NOV-2008 the patient delivered her baby and both the mother and the baby were fine. No adverse effect reported. No lab diagnostics studies were performed. Follow-up information has been received from a licensed practical nurse, for GARDASIL, a Pregnancy Registry product, concerning a 19 year old female patient with no medical history and no concurrent medical conditions and a history of 1 pregnancy and 1 live birth with no birth defects or infant complications in previous pregnancy. Who on 29-AUG-2007 and on 02-NOV-2007 was vaccinated with the first and second doses of GARDASIL. On 29-FEB-2008, the patient received the third 0.5 mL dose of GARDASIL intramuscularly. Concomitant therapy included Tdap and prenatal vitamins (unspecified). On 11-NOV-2008 the patient had a cesarean section due to prolonged labor and delivered a normal, healthy female baby with no congenital anomalies weighing 7 pounds, 4 ounces, 20 in length, head circumference 33cm, and APGAR score of 9/9. There was not complication during pregnancy, and not infections or illness during pregnancy for the patient. There was not diagnostic test during pregnancy. Upon internal review, prolonged labor was considered to be an other medically important event as it resulted in a cesarean section. Additional information is not expected.

Other Meds: vitamins (unspecified)

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357310-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	27-Aug-2009	08-Sep-2009	12	15-Sep-2009	25-Sep-2009	CA		23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF551BA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Pt given GARDASIL left deltoid on 9/27/09. On 9/8/09 Pt developed numbness under left upper arm/axilla. Exam normal except paresthesia under left axilla/upper arm.

Other Meds: ORTHOTRICYCLEN LO.

Lab Data:

History: Anemia in past .

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357338-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Aug-2009	31-Aug-2009	0	15-Sep-2009	29-Sep-2009	CA		29-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: 12yr female who had a syncope spell about a mt after receiving HPV #2.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357350-1 (S)** **Related reports:** 357350-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Aug-2007	12-Apr-2009	600	15-Sep-2009	21-Sep-2009	MI		12-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208F	3	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Back pain, Chest pain, Dyspnoea, Pulmonary embolism, Pulmonary thrombosis

Symptom Text: Blood Clot in lung on 4-12-2009 and will have to be on blood thinners rest of her life. She is currently on 15mg of warifin daily to keep her blood thinned between 2-3 INR. ```MR and DC summary received 01/07/10 for DOS 04/15/09-04/15/09. Pt c/o L side chest pain, radiating to L lower back and SOB. Assessment: L lower lobe pulmonary embolism, leukocytosis, L chest pain and back pain. Tx: heparin. Pt discharged home.

Other Meds:

Lab Data: Was in Hospital for 5 days, they ran all the relevant test for blood clots. Then went to clinic, and they ran numerous tests related to blood clots and she does not have any risk factors associated with blood clotting. ```Labs and DX stu

History: ```PMH: morbid obesity. Allergies: none.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **357350-2 (S)** **Related reports:** 357350-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Aug-2007	12-Apr-2009	600	17-Dec-2009	18-Dec-2009	--	WAES0911USA01095	18-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208F	3	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Laboratory test, Pulmonary thrombosis

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 17 year old female with no known medical history and no known previous illness on 21-AUG-2007 was vaccinated with the fourth dose of GARDASIL (Lot # 654741/1208F) IM into the right arm. It was reported that on 12-APR-2009 the patient had blood clot in lung and would have to be on blood thinners the rest of her life. She was on 15 mg of "warfarin" daily to keep her blood thinned between 2-3 INR. The patient was hospitalized for 5 days, and they ran all the relevant tests for blood clots. Then the patient went to the clinic, and they ran numerous tests related to blood clots and the patient did not have any risk factors associated with blood clotting. The listing indicated that one or more of the events required hospitalization, was considered to be disabling and was considered to be immediately life-threatening. It was reported that the event required ER visit. The event was serious. The original reporting source was not provided. The VAERS ID # is 357350. No further information is available. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center for Biologics Evaluation and Research and was released.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357353-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Sep-2009	14-Sep-2009	0	15-Sep-2009	24-Sep-2009	OK		24-Sep-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB737BA	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB343BA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0100	0	Right arm	Intramuscular	
MMR	MERCK & CO. INC.	0424Y	0	Right arm	Subcutaneously	
VARCEL	MERCK & CO. INC.	0860Y	0	Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B039BA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2990AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Malaise

Symptom Text: Pt. stated that she didn't feel well after vaccines were given. Nurse had her lay her head down on desk. She then said she was feeling worse, she did lose consousness briefly(10-15sec.) Her father helped move her to the floor, where cold pack was placed on her neck and feet were elevated. When she was able, she also was given a juice drink.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357355-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Sep-2009	14-Sep-2009	0	15-Sep-2009	24-Sep-2009	GA		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	UNKNOWN MANUFACTURER	AHAVB327AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y		Left arm	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	AC52B041BA		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1531X		Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Client was given a Tdap on 2/6/09 and 9/14/09

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **357357-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Sep-2007	01-Oct-2007	24	15-Sep-2009	24-Sep-2009	HI		10-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0469U	3	Unknown	Unknown	HEP

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Activated partial thromboplastin time prolonged, Agoraphobia, Angiogram, Anti-cyclic citrullinated peptide antibody positive, Antinuclear antibody positive, Antiphospholipid antibodies, Anxiety, Arthralgia, Cardiac stress test, Chest pain, Confusional state, Dizziness, Dyspnoea, Electrocardiogram, Electrocardiogram ambulatory, Electrocardiogram ambulatory normal, Electroencephalogram abnormal, Exercise electrocardiogram, Fatigue, Haematemesis, Lymphocyte count decreased, Major depression, Mass, Melaena, Mixed connective tissue disease, Musculoskeletal discomfort, Neutrophil count increased, Nuclear magnetic resonance imaging brain normal, Oxygen saturation decreased, Panic disorder, Raynauds phenomenon, Respiratory disorder, Rheumatoid arthritis, Skin papilloma, Smear cervix abnormal, Systemic lupus erythematosus, Thrombosis, Tremor

Symptom Text: The first two vaccines were no extreme signs,...just some minor ones like light headed, but after the 3rd vaccine the problems started within the following month. Reactions likes: shaking, anxiety, chest pain, trouble breathing, confusion, wart outbreak, blood issues (clotting and low oxygen levels) and later Dr's believe she has lupus and Rhuematoid arthritis. She also just had a fibroma tumor removed from the same foot that had the large wart develop although different area. 10/26/09: Outpatient medical records received for dates of service 2/6/08 to 10/5/09. Dx: Mixed connective tissue disease, Major depressive disorder, Panic disorder with agoraphobia, Pap smear abnormal + HPV, Respiratory abnormality NEC, Anxiety state NOS, Raynaud's syndrome. Assessment: Presents with persistent arthralgias of the hands and wrists, fatigue and achiness in neck without swelling. Had positive ANA, placed on Plaquenil. Also had positive lupus anticoagulant, but a subsequent test was negative. Started on Methotrexate weekly with positive results. Left forefoot soft tissue mass excision performed, pt. healing well at 4 weeks post op. Also had episode of hematemesis, and melena, endoscopy was normal. C/o body shakes, EEG-Abnormal. Also c/o dyspnea at times, 24 hour Holter monitoring was normal with no correlation between rhythm changes and reported dyspnea. Tendancy to desat. to 92% with exertion, though treadmill stress test was WNL; started on Advair and albuterol. Pt. has acne vulgaris and peringual warts. Additional meds.: Buspirone, Lexapro.

Other Meds:

Lab Data: Vaccine dates: Feb 27/07, Apr 27/07, Sept 07/07 10/26/09: Outpatient medical records received for dates of service 2/6/08 to 10/5/09. Labs and diagnostics: ANA-Positive, anti-CCP ab.-Positive, anti RNP ab.-Positive, CRP-Negative, Lupus

History: 10/26/09: Outpatient medical records received for dates of service 2/6/08 to 10/5/09. PMH: Eye surgery for esophoria, wisdom teeth removal, Allergic to Amoxicillin.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **357361-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Apr-2008	Unknown		15-Sep-2009	24-Sep-2009	NC		16-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	1448U	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0802U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Abdominal pain lower, Aggression, Agitation, Anxiety, Anxiety disorder, Asthenia, Convulsion, Depression, Disturbance in attention, Electroencephalogram normal, Feeling abnormal, Gastritis, Hallucination, auditory, Headache, Hyperventilation, Lethargy, Mental disorder, Mydriasis, Oppositional defiant disorder, Pain in extremity, Personality change, Personality disorder, Presyncope, Refusal of treatment by relative, Suicidal ideation, Syncope, Tremor, Unresponsive to stimuli, Urine analysis abnormal

Symptom Text: Grandmother/guardian reports headache every day for 4 days after 1st HPV dose on 04/01/2008. Menactra also given that day. Then frequent headaches - 2-3 times/week. After 2nd dose of HPV on 05/29/2008 child complained of "not feeling right". Grandmother reports she had "low energy" and a change in personality. On 09/02/2008 Child had an episode of unresponsiveness and was transported to hospital by EMS. Hospitalized 09/08-09/09 for episodes of unresponsiveness. Seizures ruled out. 9/18/09 Medical records (Middle School) DOS 3/14/08 to 11/14/08. Presents with painful finger. Lower abdominal pain. Constipation. Dysuria. Reports frontal H/A 8/20/08. Found unresponsive 8/29/08 and 9/2/08. Would not open eyes. Responded after ~10 minutes. Assessment: Unresponsive. ? syncope ? hyperventilation. On 9/11/08 found slumped in chair, pupils dilated. Assessment: syncope. 9/30/08 parent declines HPV#3. Frequent headaches. Repeated episodes of syncope. Whole body shakes. Anxiety. "Attacks of lethargy'. Burning sensation from mid abdomen "up to heart." Gastritis. Found lying on floor in class, parent refused to have patient transported by EMS and took her home. 11/10/09 Medical records and discharge summarries received as follows: Discharge summary received for DOS 10/02/09-10/07/09. Final DX: Depression NOS, PTSD, Severe Psychological Stressors, GAF 45 Patient w/increased suicidal ideation. Threatened to kill herself with knife. Auditory hallucinations. Prior admit for black out spells post vaccine. EEG normal. anorexia. low energy and poor concentration. D/C to home. Condition guarded. Follow up w/psych . DIscharge summary received for DOS 9/19/09-9/25/09. Final DX: PTSD, Depression NOS, Oppositional Defiant Disorder, Extreme psychosocial Stressors, GAF 35. Admit for in creased aggression and agitated outbursts. Discharge to home. Stable. Guarded prognosis. Discharge summary received for DOS 9/04/09-9/05/09. Final, . DX: Non epileptic seizures, Normal EEG, Depression, Anxiety, PTSD. Present

Other Meds:

Lab Data: MRI on 09/10/2009. 9/18/09 Medical records (Middle School) DOS 3/14/08 to 11/14/08. LABS and DIAGNOSTICS: Proteinuria. CMP and CBC WNL.

History: 9/18/09 Medical records (Middle School) DOS 3/14/08 to 11/14/08. Ankle sprain. Nasal Congestion. Strep Throat. Allergies: none PMH: Sexual abuse age 2 and raped within last 6 mos. Mother is bipolar and has sociopathy/ drug and alcohol dependency. Forced to take drugs by mother

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357362-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Sep-2009	14-Sep-2009	0	15-Sep-2009	24-Sep-2009	FL		24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	OZ16Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypotension, Vision blurred

Symptom Text: Dizzines,Hypotension,Blurred Vison,Quickly Recovered

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **357365-1 (S)** **Related reports:** 357365-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Mar-2008	Unknown		15-Sep-2009	21-Sep-2009	TN		06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Compression fracture, Convulsion, Epilepsy, Joint dislocation, Loss of consciousness, Muscle twitching, Myoclonic epilepsy, Myoclonus, Presyncope, Syncope

Symptom Text: Patient had the 1st shot of Gardasil on 3/17/2008, she had the 2nd shot of Gardasil on 5/19/2008. She did not have the 3rd shot. She stated having twitching spells after awakening. We thought it was just maybe the way she was sleeping because it did not happen everyday. On 8/15/2008 she had a major seizure and was admitted to the hospital. She was diagnosised with EPILEPSY. She has had 5 major seizures since and sees a neurologist on a regular basis. Diagnosis of JUVENILE MYOCLONIC EPILEPSY. She now takes LAMICTAL 300mg twice daily. She has regular EEG's. There is no history on either side of the family of a seizure disorder and she has never had any seizure history and no major illnesses. Via the Neurologist this may affect her for the rest of her life.
DID THE GARDASIL CAUSE THIS??????? 9/29/09 MR received for DOS 8/15-16/2008 with D/C DX: Seizure activity. Right shoulder dislocation. Syncope. Pt presented after witnessed seizure activity. Pt found passed out in bathtub. Pt dislocated/fractured her shoulder during the episode. Reports pre-syncopal episodes for ~6 months. ICD9: 780.39, 812.09 10/2/09 Neurology consult records received DOS 9/14/09. Assessment: Juvenile myoclonic epilepsy. Seizures occur upon awakening, initial myoclonic jerks.

Other Meds: none

Lab Data: EEG's (5 or 6) only the last 2 have shown normal with medication. Tested on a regular basis since 8/15/2008. Labs and Diagnostics: EEG abnormal-c/w seizure d/o. Ct brain (-). WBCs 18K. BS 119. shoulder X-ray (+) dislocation and compr

History: none. Dislocated shoulder, irregular periods. Migraine headaches, appendectomy.

Prex Illness: none

Prex Vax Illns: none~ ()~~0.00~Patient|none~ ()~~0.00~Sibling|none~ ()~~0.00~Sibling

Vaers Id: **357365-2 (S)** **Related reports:** 357365-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-May-2008	15-Aug-2008	88	01-Dec-2009	02-Dec-2009	--	WAES0911USA01102	04-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Compression fracture, Convulsion, Epilepsy, Joint dislocation, Loss of consciousness, Muscle twitching, Myoclonic epilepsy, Myoclonus, Presyncope, Syncope, Upper limb fracture

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 16 year old female with a history of dislocated shoulder, irregular periods, migraine and appendicectomy who on 17-MAR-2008 was vaccinated in right arm with the first dose of GARDASIL (LOT# 659653/1448U). On 19-MAY-2008 the patient was vaccinated with the second dose of GARDASIL. The patient did not have the third dose of GARDASIL. On an unknown date, the patient stated she had twitching spells after awakening. The reporter thought that it was just might be the way the patient was sleeping because it did not happen everyday. On 15-AUG-2008 the patient had a major seizure and was admitted to the hospital. She was diagnosed with epilepsy. She had 5 major seizures since and saw a neurologist on a regular basis. The patient was diagnosed with Juvenile myoclonic epilepsy. She took LAMICTAL 300 mg twice daily. The patient had regular electroencephalography (EEG). There was no history on either side of the family of a seizure disorder and she had never had any seizure history and no major illnesses. Neurologist commented that this might affect her for the rest of her life. Since 15-AUG-2008 the patient was tested on regular basis. EEGs showed abnormal which were consistent with seizure disorder. EEGs were done in 5 or 6 times and only the last 2 had shown normal with medication. The result of Computed axial tomography brain was negative. White blood cell count was 18 and blood sugar was 119. Shoulder x-ray had a positive result of dislocation and compression. On 29-SEP-2009 medical record was received for date of service on 15-Aug-2008 and 16-Aug-2008 with discharge diagnosis of seizure activity, right shoulder dislocation and syncope. Patient presented after witnessed seizure activity. She found passed out in bathtub. Patient dislocated/fractured her shoulder during the episode. It was also reported pre-syncopal episodes for 6 months. On 02-OCT-2009 neurology consult records were receiv

Other Meds: Unknown

Lab Data: electroencephalography, EEG's (5 or 6): only the last 2 have shown normal with medication; electroencephalography, EEG abnormal-c/w seizure d/o; head computed axial, (-); joint X-ray, should x-ray (+) dislocation and compr; WBC count, 18 K;

History: Dislocated shoulder; Irregular periods; Migraine; Appendicectomy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357372-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Sep-2009	15-Sep-2009	0	15-Sep-2009	24-Sep-2009	DE		28-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Fatigue, Headache, Hypoaesthesia, Nausea, Neurological examination normal, Neurological symptom, Paraesthesia

Symptom Text: within 20 minutes of shot, became dizzy with nausea and headache. left arm, hand and both feet went numb. nausea and headache ended within few hours. numbness in hand and both feet still exists 8 hours later. this was 2nd of the 3 doses. 9/25/09 Neurology consult received DOS 9/17/09. Assessment: Focal neurological symptoms after second HPV vaccine. Patient reports numbess for several hours in injected arm. Developed headache, nausea, and dizziness. Subsequently tingling sensation in left hand. Tired. Numbness in both feet. Tripped. Neurological exam - normal.

Other Meds: none

Lab Data:

History: none. Numbness after taking Percocet.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **357381-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Dec-2008	01-Dec-2008	0	15-Sep-2009	15-Oct-2009	OR		15-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	02820AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0570X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: On 12/1/08 patient given GARDASIL #2 and MENACTRA. Within 5 min. experienced joint pains. No arthritis developed, but arthralgia persisted x 3 months, treated with NSAID. Rheumatologist, not sure of cause and effect but said adverse reaction was a possibility.

Other Meds: CELEXA 20mg /day to treat anxiety

Lab Data: CBC, sed rate normal.

History: Anxiety - started CELEXA 10/27/08

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357402-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Sep-2009	15-Sep-2009	0	15-Sep-2009	16-Oct-2009	SC		02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Migraine, Pallor, Visual acuity reduced, Vomiting

Symptom Text: Received 3rd dose HPV vaccine in office this am, then went to school and within 1 hour developed severe HA. Then complained could not see out of one eye and subsequently vomited. Has been having migraine like HA since school started. Pt pale on exam here but otherwise normal.

Other Meds: MOTRIN

Lab Data: Exam; vision eval

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357428-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Feb-2008	14-Feb-2008	13	16-Sep-2009	17-Sep-2009	FR	WAES0909USA01423	17-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Complication of delivery, Drug exposure during pregnancy

Symptom Text: This is a case of pregnancy follow-up reported by a general practitioner through the GARDASIL pregnancy registry. Initial report on 06-MAR-2008: A 17 year old female started a spontaneous pregnancy (estimated conception date: 15-FEB-2008) 5 days after receiving a dose of GARDASIL (batch number not reported) on 10-FEB-2008. She had no medical or obstetric history, estimated delivery date was 15-NOV-2008. No adverse effect was reported. Follow-up information received through the GARDASIL pregnancy registry initial questionnaire: Vaccination date was reported as 01-FEB-2008 (previously reported as 10-FEB-2008). Estimated date of conception was 14-FEB-2008. Echographies at 12, 22 and 32 amenorrhea weeks normal. The patient had no amniocentesis. Follow-up information received through the outcome pregnancy questionnaire on 08-JAN-2009: Case upgraded to serious. There was no complication during the pregnancy. Diagnostics performed during pregnancy were normal. There was no infection and no disease during pregnancy. there were no complication during labor and the patient had a caesarean section on 30-OCT-2008. She gave birth to a normal baby girl at 38 amenorrhea weeks. Baby's height was 46cm, weight was 2kg835, cranial perimeter was 33cm. Follow-up information received by telephone on 10-SEP-2009: It was confirmed that the baby was in good health with no particular problems. Complication of delivery was considered to be an other important medical event by the general practitioner. No further information expected. Other business partner numbers included E2008-02173.

Other Meds: Unknown

Lab Data: ultrasound, at 12 amenorrhea weeks was normal; ultrasound, at 22 amenorrhea weeks was normal; ultrasound, at 32 amenorrhea weeks was normal

History:

Prex Illness: Pregnancy NOS (LMP = 14Feb08)

Prex Vax Illns:

Vaers Id: 357429-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Nov-2007	01-Sep-2008	279	16-Sep-2009	17-Sep-2009	FR	WAES0909USA01383	17-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0277U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune thrombocytopenia, Biopsy bone marrow, Cytology, Reaction to previous exposure to any vaccine

Symptom Text: Case received from health authority in a foreign country on 08-SEP-2009 under HA reference no. PEI2009019595. This case is linked with non serious case E2009-08535 (same reporter, same product, same patient, different reaction after D1). It was reported that a 15 year old female patient was vaccinated with a third dose of GARDASIL (batch number NG00020, Lot#0277U) IM, injection site not reported, on 27-NOV-2007. Nine months p.v., on 01-SEP-2008, the patient developed autoimmune thrombocytopenia (Werlhof's syndrome coded by HA PEI). On 02-JUL-2009 bone marrow biopsy and cytology were done but results were not reported. At the time of report to HA (04-SEP-2009) the patient was not recovered. Patient showed tinnitus, headache and concentration disturbances on 01-AUG-2007 after D1 of GARDASIL (batch NE38100, Lot#654948/0903F) administered on 31-MAY-2007. D2 of GARDASIL (Lot# not reported) on 08-AUG-2007 was well tolerated. The agency considered the event to be serious for the following reason: medically significant. Other business partner numbers included E2009-08534.

Other Meds: Unknown

Lab Data: Unknown

History: Tinnitus; Headache; Concentration impaired

Prex Illness:

Prex Vax Illns:

Vaers Id: **357430-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Sep-2009	17-Sep-2009	--	WAES0909USA01369	17-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paralysis

Symptom Text: Initial and follow-up information has been received from a physician's assistant concerning a patient's family member who on an unspecified date was vaccinated with a dose of GARDASIL. The physician's assistant mentioned that the patient experienced paralysis waist down. She also stated she did not know the patient's name or any information concerning the patient. The physician's assistant stated her patient had reported that the patient's cousin had heard that there was a patient who received GARDASIL and had paralysis from the waist down. The physician's assistant did not remember the patient's name that had reported the incident to her. Upon internal review paralysis is considered to be other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 357434-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	09-Sep-2009	09-Sep-2009	0	16-Sep-2009	28-Sep-2009	MD		23-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0670Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Feeling abnormal, Headache, Pain in extremity, Pyrexia

Symptom Text: 9-9-09 - Pt received 3rd GARDASIL vaccination approximately equal to 1:10pm. Approx. 4 hours later, began to "feel funny" and was making "non-lucid statements" while at work. Went home to bed. Woke 9/10/09 approximately equal to 1:00am with headache, mild shortness of breath and low grade fever (100.9). Left arm sore. Advised to go to ER - Pt triaged at ER, waited "4.5 hr" and left prior to being seen by MD. 9-11-09 - Pt reports feeling better. 9-15-09 - Fu call to pt, states "feeling fine". No further complaints.

Other Meds: None

Lab Data: None

History: Migraine; Eczema, atopic

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357458-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	U	15-Sep-2009	15-Sep-2009	0	16-Sep-2009	28-Sep-2009	CA		29-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Patient reported a hive-like rash to arms 1 hour after receiving 2nd Guardasil Vaccine on 09.15.09. Rash lasted 10 minutes & resolved without treatment

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **357469-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Sep-2009	11-Sep-2009	1	16-Sep-2009	28-Sep-2009	WA		29-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	96030 4P	1	Left arm	Intramuscular	
	PNC7	WYETH PHARMACEUTICALS, INC	D48928	9	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0671Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dizziness, Nausea, Pain in extremity, Pyrexia, Wrong drug administered

Symptom Text: Pt was to receive Gardasil #1, Fluvirin, and Menactra. She did receive Gardasil and Fluvirin but was given Prevnar in error. Had soreness of both arms the day of injection. The next morning she developed fever initially to 100.2F, chills, and dizziness. Over the next 3 days she had fever to 102F, and nausea as well.

Other Meds:

Lab Data:

History: short stature

Prex Illness: none

Prex Vax Illns:

Vaers Id: 357474-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Aug-2009	05-Sep-2009	24	16-Sep-2009	21-Sep-2009	WA		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB311AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Headache, Hyperaesthesia, Lymphadenitis, Lymphadenopathy, Malaise, Muscle spasms, Musculoskeletal stiffness, Myalgia, Myositis, Phonophobia, Photophobia, Viral infection

Symptom Text: at 25 days after shot she developed the worst headache of her life 10/10, swollen glands in her neck, malase, significant hypersensitivity to touch, myalgia and myositis. She was hospitalized for 4 days with negative work up for any infection, menningitis or known viral illness. She was on multiple narcotic and non narcotic pain medications that did not help her pain. 9/17/09 Received hospital medical records for 9/9-9/12/20009. FINAL DX: headache, neck stiffness, & abdominal pain Records reveal patient experienced HA & neck stiffness x 6 days w/photophobia/phonophobia & abdominal pain x 1 day. Tx w/IVF, pain & nausea meds, IV antibiotics, & oral steroids. ENT consult done & dx w/cervical lymphadenitis secondary to viral syndrome & muscle spasms. D/C to home w/PCP f/u, on pain meds & steroid taper.

Other Meds:

Lab Data: Negative LP, Mono spot, EBV titers, Strep Screen, CBC, CMP, UA, CMV titers, Mumps titers. 9/17/09 Received medical records w/LABS: CBC, CMP, CSF, mono & UA all WNL. Throat c/s (+) grp B strep.

History: LACTOSE INTOLERANCE 9/17/09 Received medical records w/PMH: Allergy: PEN.

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: 357475-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jul-2009	18-Jul-2009	2	16-Sep-2009	29-Sep-2009	TX		29-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3097AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1584X	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2914AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0342Y	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy, Musculoskeletal pain, Pain, Pain in extremity

Symptom Text: Per mother, pt awoke on Saturday, 7/18/09, with pain in right arm and neck with lumph node swollen like cyst. Per mother, pain pt had shooting pain from shoulder blade down right arm. No redness noted. Pt taken to ER and told could have been reaction to vaccines. Mother states pt given a medication to take for ten days, and pt was better three days after ER visit. Mother does not remember what medication was. Mother states pt to continue HPV series with personal physician.

Other Meds: unknown

Lab Data: unknown

History: unknown

Prex Illness: none known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357491-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Sep-2009	10-Sep-2009	1	16-Sep-2009	28-Sep-2009	CA		29-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2814AA	1	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0682Y	1	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB173AA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Injection site erythema, Injection site swelling

Symptom Text: Redness & swelling to site. Doctor visit. Dx cellulitis approximately Tx AMOXIL 500 T TID X 7 days.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 357495-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Jul-2009	03-Aug-2009	3	16-Sep-2009	20-Oct-2009	CA		20-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	03134	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Similar reaction on previous exposure to drug

Symptom Text: Nausea, dizziness (Patient received a dose of GARDASIL 1st dose on 3/22/09, 2nd dose on 7/31/09 similar symptoms after each of these doses).

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 357516-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	14-Aug-2007	01-Oct-2007	48	17-Sep-2009	18-Sep-2009	MA	WAES0907USA04940	02-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0469U	1	Right arm	Intramuscular	HPV4

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Asthenia, Fatigue, Headache, Increased tendency to bruise, Infection, Migraine, Myalgia

Symptom Text: Information has been received from a registered nurse concerning her daughter who had been vaccinated with three doses of GARDASIL and after the second dose began experiencing headaches. The patient was not hospitalized. The patient was seeing a rheumatologist. Follow-up information was received from a 23 year old female patient. She reported she in June 2007, August 2007 and December 2007 was vaccinated with the first, second and third dose of GARDASIL (lot numbers not reported) respectively. There was no illness at time of vaccination and there was no pre-existing allergies, birth defects or medical conditions either and "she was never a sick child or a sick adult". On 01-OCT-2007 morning the patient started to experience migraines. The patient reported she had constant migraine since then. She had seen a neurologist multiple times. She had an MRI, and MRV and and MRA done in late 2007 and they all showed no complications. She had been prescribed amitriptyline hydrochloride, ZOMIG, FROVA, FIORICET, TOPAMAX, INDERAL, lisinopril among others, not one of these medications helped her migraines. she saw her original primary care doctor and now being followed by her new primary care physician. She had multiple infections, many times getting tested for Lyme disease (negative) and other blood tests (negative). She was in constant crippling pain from her migraines, as well as muscle joint pain and weakness, and frequently getting infections. She had been bruising especially easily since October 2007 also. She was tested for VON WILLEBRAND'S Disease, but results were negative here as well. Her new primary doctor had recently diagnosed her with chronic fatigue and referred her to a Rheumatologist, which she had scheduled an appointment. The patient strongly believe her symptoms are side effects caused by the GARDASIL vaccine. She reported she had none of these symptoms prior to receiving the vaccine, and there was no medical explanation to her symptoms as of yet. The patient was not recovered. The patient's events were co

Other Meds: Unknown

Lab Data: magnetic resonance, ?/?/07, no complications; vascular imaging, ?/?/07, no complications; diagnostic laboratory, negative; MRV, ?/?/07, no complications; Lyme disease assay, negative; von Willebrand factor, negative

History: None HPV#3 given 12/14/07, Lot# 0890F, RA

Prex Illness:

Prex Vax Illns:

Vaers Id: 357517-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	24-Aug-2008	28-Jul-2009	338	17-Sep-2009	18-Sep-2009	PA	WAES0909USA01170	18-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Confusional state, Convulsion, Drug hypersensitivity, Headache, Oral contraception, Speech disorder, Tongue biting

Symptom Text: Initial information from a consumer with follow up information from a secretary at a physician's office, concerning a 24 year old female with warts and no known drug allergies who on 24-AUG-2008 was vaccinated with the first dose of GARDASIL (lot# 660553/0070X), 0.5 ml, I.M. and on 16-OCT-2008 was vaccinated with the second dose of GARDASIL (lot# 660612/0229X) 0.5 ml, I.M. Concomitant therapy included ALDARA for warts and "kapara" 500 mg daily. The patient had been off the birth control pill since January 2009. The physician noted in the chart for the 09-SEP-2009 visit, "The patient reported new onset of seizures since starting GARDASIL". Upon internal review seizures were considered to be an other important medical event. The health care professional contacted during telephone follow-up could not supply the following information: date of event, recovery status, hospital name (if applicable), primary practitioner contact information. Additional information has been requested. 9/28/09 PCP medical records received DOS 8/24/08 to 9/18/09. Patient experienced new onset seizure after Gardasil. Genital warts resolved. Reports Augmentin allergy. Oral contraception. 12/7/2009 and 12/14/2009 ED records for 7/28-7/29/2009 and neuro f/up visit for 7/31/2009. Patient with c/o's confusion, biting the tongue, short term memory loss, headache and difficulty with speech after waking today. Patient had a similiar incident 4/2009 but did not seek tx. Neuro consult in hospital, started on Keppra. Dc Dx seizure disorder/Epilepsy

Other Meds: ALDARA. 9/28/09 PCP medical records received DOS 8/24/08 to 9/18/09. Oral contraception.

Lab Data: Unknown Labs: CBC, wbc high, neutro high, lymphs and monos low, CMP, high glucose, potassium low, cardiac enzymes, Lyme titer norm, CPK, UA, Urine HCG, and urine drug screen all negative Dx studies: CT head, EKG, EEG wnl, MRI brain noted

History: PMH: None Allergies: NKDA

Prex Illness: Wart. Genital warts.

Prex Vax Illns:

Vaers Id: 357518-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jan-2009	06-Aug-2009	202	17-Sep-2009	18-Sep-2009	FR	WAES0909USA01202	18-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1145U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Bone pain, Condition aggravated, Epilepsy, Pain in extremity

Symptom Text: Information has been reported on 02-SEP-2009 by the mother of the patient and additional information was reported by the mother on 07-SEP-2009 and by healthcare professional on 09-SEP-2009. It was reported that a 17 year old female was vaccinated with the third dose of GARDASIL (Batch# NJ11570, LOT# 1864U) on 10-JUL-2009. The first and second dose of GARDASIL was given on 16-JAN-2009 (Batch# NH01650, LOT# 1145U) and 17-MAR-2009 (Batch# NJ03220, LOT# 1881U), respectively. The mother recalled the girl being more tired than usual during spring 2009, however she was not certain whether this appeared in connection to the vaccinations or not. Patient had tuberous sclerosis and epilepsy. She was treated with PETNIDAN since March 2009 and TRILEPTAL since many years. She also had a speech disturbance making it difficult to communicate. On 06-AUG-2009 the girl developed pain in her right side that gradually translocated to the joints in the arms, legs and feet. No pain in the face, abdomen or back. There was no swelling or headache. Applying some pressure in these regions resulted in pain. With time the pain was translocating over her body. At some points she had pain in her entire thigh muscle. According to the mother the girl never complaints, however now she was very clear with where she was experiencing pain. The mother recalled that there might have been some minor epileptic attacks during the time the girl experienced the pain. The pain remained for approximately five days and then disappeared. On 12-AUG-2009 the same pain returned and once again the girl improved after five days. On 06-SEP-2009 the pain once again appeared. This time the pain was localized to the feet and the tibia bone. The patient was not recovered at the time of the report. This case was considered to be serious due to other important medical event. Other business partner numbers included: E2009-08531. No further information is available. Case is closed.

Other Meds: PETNIDAN, Mar09; TRILEPTAL

Lab Data: Unknown

History:

Prex Illness: Tuberous sclerosis; Epilepsy; Speech disorder

Prex Vax Illns:

Vaers Id: 357519-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Jun-2009	01-Jul-2009	16	17-Sep-2009	18-Sep-2009	PA	WAES0909USA01378	06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Idiopathic thrombocytopenic purpura

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a 16 year old female with no pertinent medical history or drug reactions who was vaccinated with at lease one dose of GARDASIL (lot#, route and site of administration not reported) in the last 4 weeks. Concomitant therapy included prenatal vitamins. The patient was pregnant and developed immune thrombocytopenia purpura. On approximately 14-AUG-2009 ("4 weeks ago"), the patient's platelet level, 8000/L, was extremely low. On 04-SEP-2009 she started with treatment with prednisone 20 mg, twice daily. Her platelet level was already 116000/L. Other than the low platelet the patient was asymptomatic. At the time of this report, the patient had not recovered. The patient's "due date" was 20-APR-2010. Follow up information has been received from a registered nurse who stated that on 23-AUG-2009 the 16 year old female patient was in a fight and received an injury to her eyes and head. The patient was 7.5 weeks pregnant at the time. She underwent a CT of the head (hospital location and results not available). No blood work was done at that time. On 04-SEP-2009 her blood work was drawn and the platelet result was 8000. The patient was diagnosed with immune thrombocytopenia purpura. Additional follow up information has been received from a licensed practical nurse concerning the 16 year old female patient who on 15-JUN-2009 was vaccinated with the first dose of GARDASIL (lot# 659441/1446U, route and site of administration not reported). On 17-AUG-2009 she was vaccinated with the second dose of GARDASIL (lot#661953/1130X, route and site of administration not reported). No other vaccines were administered on these two dates. Upon internal review, the immune thrombocytopenia purpura was determined to be an other important medical event. Additional information has been requested. 10/01/09 Received PCP medical records. FINAL DX: Idiopathic Thtombocytopenic Purpura Records reveal patient in usual state of good health on 6/15

Other Meds: vitamins (unspecified)

Lab Data: complete blood cell, 09/04/09, 8000 /L; complete blood cell, 09/??/09, 11600 /L

History: 10/1/09 Medical records received w/PMH: childhood chickenpox. smoker. HPV #2 received 8/17/2009, Lot # 1130X, LA.

Prex Illness: Pregnancy NOS (LMP = 7/1/2009)

Prex Vax Illns:

Vaers Id: **357520-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2009	18-Sep-2009	--	WAES0909USA01466	18-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Human papilloma virus test positive, Precancerous cells present

Symptom Text: Information has been received from a physician assistant concerning several "30's" female patients who were vaccinated with GARDASIL series on unspecified date and a couple of years later test positive for HPV. There patients had gone to an office and had Pap's that came back as high risk. These were precancerous cells. The reporter mentioned most of these patients were married. The reporter thought the patients test that came back as high risk were for the HPV types that GARDASIL did not cover. One of these patient's physicians "froze the precancerous cells". The number of patients was unknown. At the reporting time the outcome was unknown. Upon internal review, precancerous cells and test positive for HPV were determined to be other important medical events. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **357521-1** **Related reports:** 357521-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Aug-2009	21-Aug-2009	0	17-Sep-2009	18-Sep-2009	--	WAES0909USA01474	15-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1605X	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0311Y		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2918AA		Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0865Y	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3246BA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Epilepsy, Immediate post-injection reaction

Symptom Text: Information has been received from a physician's assistant concerning a 14 year old female with a history of a seizure when she was 10 years old who on 21-AUG-2009 was vaccinated with a 0.5 mL dose of GARDASIL (lot # 659054/0311Y). Secondary suspect vaccination given on the same date included doses of VARIVAX (Merck), VAQTA (Merck), MENACTRA, and ADACEL. The patient had a seizure right after getting the vaccinations. She was taken to the emergency room and was given phenytoin 100 mg BID (manufacturer/description unknown). They wanted the patient to follow up with a neurologist. Therapy with GARDASIL Was discontinued. Subsequently, the patient recovered from seizure. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested. 9/25/09 PCP medical records received DOS 8/21/09. Assessment: Unspecified epilepsy without mention of intractable epilepsy. Patient was sent to ER for seizures after vaccine administration. 12/9/09 Received ER medical records of 8/21/09. FINAL DX: Records reveal patient very scared of receiving shot & experienced seizure like activity same day. Not on seizure meds. Dilantin restarted, d/c to home & referred to PCP 12/16/09 Medical records received for dates 9/3/09 to 9/16/09 DX: seizure disorder. Pt presented w/ seizure after gardasil vax dose 1. ER recs received for date 8/21/09 DX: seizure. pt was receiving vax, pt stated scared of needle, and had aseizure.

Other Meds: Unknown

Lab Data: Unknown. 9/25/09 PCP medical records received DOS 8/21/09. LABS and DIAGNOSTICS: PPD - Results pending. Diag/Labs: EEG(-)

History: Convulsion. 12/9/09 Received ER medical records of 8/21/09 w/PMH: seizures 4 yrs prior.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357521-2** **Related reports:** 357521-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Aug-2009	21-Aug-2009	0	05-Oct-2009	06-Oct-2009	--	200904016	06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0311Y		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Initial report received on 22 September 2009 from another manufacturer (report number WAES 0909USA01474) who had received the original report from a physician's assistant. The following is verbatim from the other manufacturer's report. "Information has been received from a physician's assistant concerning a 14 year old female with a history of a seizure when she was 10 years old who on 21-AUG-2009 was vaccinated with 0.5 mL dose of GARDASIL (lot # 659054/0311Y). Secondary suspect vaccination given on the same date included doses of VARIVAX (Merck), Hepatitis A virus vaccine inactivated (manufacturer unknown), MENACTRA and ADACEL. The patient had a seizure right after getting the vaccinations. She was taken to the emergency room and was given phenytoin 100 mg BID (manufacturer/description unknown). They wanted the patient to follow up with a neurologist. Therapy with GARDASIL vaccine was discontinued. Subsequently, the patient recovered from seizure. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested." Documents held by sender: None.

Other Meds: Unknown

Lab Data: Unknown

History: History of seizure when patient was 10 years old.

Prex Illness:

Prex Vax Illns:

Vaers Id: 357525-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Aug-2009	26-Aug-2009	0	17-Sep-2009	18-Sep-2009	--	200903872	18-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC526046AA		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2815A		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	AC526046AA		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fatigue

Symptom Text: Initial report received on 08 September 2009 from another manufacturer, report # WAES0908USA04708 whose initial reporter was a health care professional. "Information has been received from a physician and an office manager concerning a 12 year old female patient with amoxicillin allergy who on 26-AUG-2009 was vaccinated with the first 0.5 ml dose of GARDASIL, concomitantly with a dose of (BOOSTRIX) (Lot : AC528046AA), a dose of VARIVAX (Lot : 664232/0498Y) and a dose of (MENACTRA) (Lot: U2815AA). The patient stated that after the vaccination she felt tired. She went home and had a seizure. the patient went to the emergency room and had computed axial tomography (CAT) done (results not reported). The patient was not hospitalized. The patient's mother called on 27-AUG-2009 at the physician's office and stated that her daughter was doing better. The physician also stated that her did not consider the events to be life threatening or to have caused the patient significant disability or incapacity. Upon internal review the seizure was considered as other important medical event. Additional information has been requested".

Other Meds:

Lab Data: 26 August 2009: computed axial tomography (CAT), (results not reported).

History: Patient has a penicillin allergy.

Prex Illness:

Prex Vax Illns:

Vaers Id: **357527-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	25-Jun-2009	28-Jun-2009	3	17-Sep-2009	18-Sep-2009	FR	WAES0909USA01564	18-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1400U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion

Symptom Text: Information has been received from a pediatrician concerning a 13 year old female who on 25-JUN-2009 was vaccinated intramuscularly into the upper arm (side not reported) with the first dose of GARDASIL (LOT#1400U, Batch#NH38510). On 28-JUN-2009 after arriving to a city per flight the patient experienced a first grand mal epileptic fit with duration of approximately five minutes. The patient recovered completely. The reporter assessed the relation to the vaccine as possible and underlined that attendant circumstances could have been stress due to holiday trip. Grand mal epileptic fit was considered to be an other important medical event. Other business partner numbers included: E2009-08565. No further information is available. File is closed.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357529-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	Unknown	Unknown		17-Sep-2009	01-Oct-2009	CA		01-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Headache, Nasal congestion, Pyrexia

Symptom Text: Cough and stuffy nose lasting more than two weeks so far; fever of 102.4, severe headache

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357536-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	20-Apr-2007	18-May-2009	759	17-Sep-2009	01-Oct-2009	PA		02-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB162CB	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0244U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Basedows disease, Goitre, Headache, Hyperthyroidism, Nausea, Palpitations, Sensory disturbance, Tachycardia, Tremor, Weight decreased

Symptom Text: pt developed Graves Disease an autoimmune disorder (rare for pt's age group) that was not diagnosed officially until Spring of 2009. 9/28/09 PCP medical records received DOS 5/18/09 to 9/2/09. Assessment: Graves Disease. Patient presents for headache behind eyes and across forehead. Nausea. Feels like something is moving in head. Fatigue. Tachycardia, enlarged thyroid gland. Weight loss. Palpitations. Slight tremor. Hyperthyroid.

Other Meds: none

Lab Data: original TSH was < 0.1. LABS and DIAGNOSTICS: Free T4 4.6 ng/dl (H) T3 672 ng/dl (H) TSI 247% (H) Thyroglobin Antibodies 74 UI/ml (H) Thyroid Stim Hormone < 0.01 uIU/ML (L). CBC - Lymph 33.8% (L) Mono 11.2% (H) Gran 52.1% CHEM - Alkaline P

History: PCN, Asthma

Prex Illness: none

Prex Vax Illns: Graves Disease~HPV (Gardasil)~3~12.00~Patient

Vaers Id: **357538-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Sep-2009	16-Sep-2009	0	17-Sep-2009	24-Sep-2009	SC	SC0923	04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B0468B	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3011AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Excoriation, Fall, Feeling hot, Gait disturbance, Immediate post-injection reaction, Visual impairment

Symptom Text: Approximately 2 minutes after receiving Tdap, MCV4 and HPV, client was observed with an unsteady gait. Client hit the side of a hallway wall with right eyebrow, right side of cheek and between nose and lip. Small abrasion observed to area between nose and lip. Client reported that she "got hot all of a sudden and could not see". Nurse was able to catch the client when falling. Client was eased to the floor. BP was taken (98/62)and a cool cloth applied to forehead, face and neck. Client was then assisted to an exam table and lower extremities were elevated. Client remained in clinic for approx. 20 minutes. Left with mother in stable condition. Instructed to go to ER if any signs of nausea, vomiting, headache, blurred vision, etc. Follow-up phone call to mom approx. 1 hour later. Mom reported client feels better.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 357541-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Aug-2007	13-Sep-2007	34	17-Sep-2009	01-Oct-2009	CT		02-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Headache, Joint swelling, Laboratory test abnormal, Nausea

Symptom Text: Extreme Fatigue, Nausea, migratory joint pain, joint swelling, abnormal TSH,T3,T4, headaches

Other Meds: Xyzal, Xopenex, Advair

Lab Data: Lyme test, JRA, Thyroid testing, CMV, EBV

History: Asthma, Uticaria Pigmentosa 9/21/09 Medical records received w/:Menactra, Lot# U237BA, given LA 9/14/07; HPV #2, Lot# 1263U given LA 10/12/2007; Fluzone, Lot# U2448AA given 11/21/07 LA

Prex Illness:

Prex Vax Illns:

Vaers Id: **357558-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Aug-2008	28-Sep-2008	31	17-Sep-2009	29-Sep-2009	ME		23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0604X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0571X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstrual disorder, Similar reaction on previous exposure to drug

Symptom Text: Patient and mother report - after HPV #1 patient skip one period. After HPV #2 skipped 2 periods and now menstrual cycle irregular.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357561-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Aug-2009	18-Aug-2009	5	17-Sep-2009	01-Oct-2009	OH		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	?	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acne, Back pain, Headache, Local swelling, Lymph node palpable, Lymphadenitis, Lymphadenopathy, Mass, Musculoskeletal stiffness, Nasal congestion, Nasopharyngitis, Neck pain, Pain, Pharyngeal erythema, Pyrexia, Scab, Torticollis, Vomiting

Symptom Text: Five days after receiving the guardisil shot in her left arm she awoke with a painful lump above her left clavicle. Ten days after the lump, she saw the doctor who ran strep and mono quick tests, both were negative. The doctor ordered E.B.titers, CBC and sed rate. All tests results were normal. On 9-3-09 she was back in the Doctor's office with low grade fever. Doctor thought it might be sinus infection and gave her Azithromycin. The lump did not go away during the course of treatment with antibiotics it just became less tender. On 9-16-09 the tenderness of the lump has increased again. The size of the lump remains the same to date. We do not know if the lump formed immediately after her shot or if the level of pain on the 5th day led her to find the lump. 9/22/09 Received PCP medical records. Visit on 8/27/09 w/neck stiffness, swelling & tenderness & left supraclavicular node x 10 days; HA & vomiting x 2 days. Also noted pimple of left cheek that enlarged & burst spontaneously then scabbed over. Dx w/Torticollis left side & cervical adenitis. All labs neg. RTC 9/3 w/cold s/s, red throat, nasal congestion & backache. Tx w/oral antibiotics. No further medical records available.

Other Meds: none

Lab Data:

History: Exercise induced asthma.Allergy to amocicillin.

Prex Illness: none

Prex Vax Illns: none~ ()~~0.00~Patient|none~ ()~~0.00~Sibling

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357576-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Sep-2009	17-Sep-2009	0	17-Sep-2009	30-Sep-2009	MI		01-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB357CA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1013Y	0	Left arm	Intramuscular	
	MMR	MERCK & CO. INC.	0706Y	2	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3044AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall

Symptom Text: Client received HPV, HAv, MCV4. Advised to stay seated. Stated she wanted to go to lobby and went.Family started to walk to WIC clinic. Started feeling light headed and slid down the wall. Did not hit head or hurt herself in any way.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357598-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Sep-2009	16-Sep-2009	0	17-Sep-2009	20-Oct-2009	OH		20-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vomiting

Symptom Text: Vaccine given on 9-16-09 @ 245/PM. Pt. developed "severe headache & vomiting overnight" (per mother)

Other Meds: None

Lab Data:

History: NKDA - Scheumam's hyphosis with Back Pain

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357621-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	12-Jun-2009	13-Jun-2009	1	17-Sep-2009	29-Sep-2009	MO		10-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Pain

Symptom Text: Per pt phone call 9/14/09, pt received HPV #2 on 6/12/09. Went to ER 6/13/09 for fatigue & body aches, unable to hold 3 mo old son. Per pt. given pain injection and sxs resolved immediately. Told @ ER sxs due to HPV vaccine.

Other Meds: Mirena IUD

Lab Data:

History: None

Prex Illness: None unknown

Prex Vax Illns:

Vaers Id: 357638-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-May-2007	Unknown		18-Sep-2009	21-Sep-2009	FR	WAES0807USA01405	21-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abnormal dreams, Alopecia, Areflexia, Diarrhoea, Dysphagia, Dysstasia, Facial paresis, Fall, Gait disturbance, Guillain-Barre syndrome, Head deformity, Headache, Lymphadenopathy, Muscular weakness, Myalgia, Pain, Paraesthesia, Paraparesis, Reaction to previous exposure to any vaccine, Sleep disorder, Speech disorder, Vomiting, Weight decreased

Symptom Text: Information has been received from a health authority (reference # PEI2008009402) concerning a 17 year old female who on 13-DEC-2007 was vaccinated with a third dose of GARDASIL (lot # not reported). On 24-APR-2008 the patient was diagnosed with GUILLAIN-BARRE syndrome. The adverse event lasted for more than one month. The reporter did not see a causal relation to the vaccine. The final outcome was not reported. Follow-up information received on 08-SEP-2009. Reporting form was provided from database of an independent information service for physicians and pharmacists, reference number 15018). Unspecified time after third vaccination the patient experienced pain of the whole body, headache, vomiting, diarrhoea, swollen lymph nodes and alopecia. Then, 3 months post vaccination, she suffered from paraesthesia in legs and hands, myasthenia in arms and legs, a singular fall due to gait disturbance and myalgia. At clinical investigation in hospital on an unknown date the patient showed distal paraparesis of the legs, loss of reflexes of the lower extremities and instable gait and stand. Diagnosis of GUILLAIN-BARRE syndrome was established. With admission laboratory test showed increased transaminases and LDH (lactic dehydrogenase), no values available. During acute phase of disease (not specified) the patient suffered from weight loss of 9 kg, physical strain due to facial paresis with facial asymmetry, speak and swallow disorder, impaired mimic, sleep disorder and abnormal dreams. After outpatient rehabilitation lasting several weeks the symptoms improved and the patient attended school again. Final outcome was not reported. Dose one of GARDASIL was given on 15-MAY-2007 and was well tolerated. After second vaccination with GARDASIL on 01-AUG-2007 the patient experienced twice syncope (see linked case E2009-08550). GUILLAIN-BARRE syndrome, facial paresis, alopecia, sleep disorder, abnormal dreams, general body pain, weight loss, diarrhoea, transaminases increased, lactate dehydrogenase increased, swollen lymph nodes, v

Other Meds: Unknown

Lab Data: diagnostic laboratory test, transaminases: increased; serum LDH, increased

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Jul-2009	21-Jul-2009	0	18-Sep-2009	21-Oct-2009	FL		21-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0685Y	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2868AA	0	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB350BA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypoaesthesia, Immediate post-injection reaction, Pallor, Peripheral coldness

Symptom Text: Within minutes of the administration of the vaccines pt became pale and felt lightheaded. She began c/o numbness in her hands with her hands feeling cold. I sat her on a chair with her head between her knees and had her breathe in a bag x 30 seconds. Soon after she began feeling better and her pallor started fading with resolution of numbness and lightheadedness. She left the office on her own accompanied by her mother.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357707-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Sep-2009	10-Sep-2009	1	18-Sep-2009	01-Oct-2009	AL	AL0919	01-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B036BA	5	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB330CA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0653X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Skin warm

Symptom Text: Redness, warmth- left arm.

Other Meds: NONE

Lab Data: N/A

History: Codeine

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357714-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Aug-2009	14-Aug-2009	0	18-Sep-2009	02-Oct-2009	NY		02-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2907BA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0698Y	2	Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	UF551AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Injected limb mobility decreased

Symptom Text: Received Tdap and Varicella and Menactra on 8/14. Started with soreness in Left shoulder soon after. Soreness and pain with movement continued and I saw her on 9/16. She was very uncomfortable with abduction and anterior rotation of L shoulder

Other Meds: MV with Fl. and received Septa on 8/28 for 10 day course

Lab Data: none so far

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 357771-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Feb-2009	21-Jun-2009	140	21-Sep-2009	22-Sep-2009	FR	WAES0909USA02058	22-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Brain stem auditory evoked response normal, Hearing impaired, Neurosensory hypoacusis, Tinnitus

Symptom Text: Information has been received from on 11-SEP-2009 from the drug safety unit at GSK, regarding a female patient, age not reported, with hyperprolactinaemia, pneumonia fungal and weight decreased and a history of perianal abscess and herpes zoster who was administered in February 2009, exact date not reported, the third dose of GARDASIL (route, site of administration and lot number not reported). The case was initially reported by a Health Care Professional to GSK drug safety unit who transmitted the case to the Health Authority (reference number: ES-GLAXOSMITHKLINE-B0582547A). Afterwards it was reported that GARDASIL and not (CERVARIX) was administered. It was reported that on 21-JUN-2009 the patient presented tinnitus after a train trip. On 26-JUN-2009, the patient had a hypoacusis sensation in the right ear. Physical exploration was normal. An audiometry was performed, results, showed a deep right ear neurosensorial hypoacusis of the right ear. During the next week the patient presented with right ear auditive level fluctuations with an improving trend, and also with a left ear moderate neurosensorial hypoacusis with a favourable evolution, finally it was reported that the patient has audiometric levels of 20 dB in both ears. Brain stem auditory evoked potential was performed on 01-JUL-2009 with normal hearing levels up to 20 dB in the left ear and 60 dB in the right ear. The results regarding evolution of potentials were still pending. Additional test performed (date not reported) were: Thyroid study LH, LSH, prolactine and estradiol. All values were normal. The patient presented with immunoglobulin G positive against CMV (pending results of the second sample). Final MRI: brain stem and acoustic pores with no significant findings. The reporter felt that Neurosensory hypoacusis, tinnitus, Auditory disorder, CMV IgG antibody positive were other important medical events. Other business partner numbers include E2009-08656. No further information is available.

Other Meds: Unknown

Lab Data: hearing test, 01Jul09, normal hearing levels up to 20 dB in the left ear and 60 dB in the right ear; magnetic resonance imaging, brain-stem and acoustic pores with no significant findings; diagnostic laboratory test, LSH-Normal values; seru

History: Perianal abscess; Herpes zoster

Prex Illness: Hyperprolactinaemia; Weight decreased; Pneumonia fungal

Prex Vax Illns:

Vaers Id: 357772-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	01-Dec-2007		21-Sep-2009	22-Sep-2009	FR	WAES0802USA00134	22-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	DTIPV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Intra-uterine death, Pre-eclampsia, Pregnancy induced hypertension

Symptom Text: Information has been received from a pregnancy follow-up report received from the Health Authorities through the GARDASIL Pregnancy Registry concerning a 16 year old female who on an unspecified date was vaccinated with GARDASIL (batch number, route and site of administration was not reported). On an unspecified date, four months after the beginning of her pregnancy (estimated conception date was not reported). No adverse reaction was reported. Follow-up information received through a telephone call on 11-SEP-2009. Case linked to serious case E2009-08663 (WAES# 0909USA01936) (Child's case). Case upgraded to serious up on the basis of the following information: The patient received a dose of GARDASIL (batch number not reported) and a dose of DT POLIO (batch number not reported) on an unspecified date, four months after the beginning of her pregnancy. Estimated conception date was 20-AUG-2007. On an unspecified onset of time, she experienced pregnancy-induced hypertension and pre-eclampsia. On 29-APR-2008, the baby died at 37 amenorrhea weeks of fetal death. There was no information on the patient's medical history, on risk factors nor on her pregnancy follow-up. At the time of reporting the patient's outcome was unknown. Upon internal review, pre-eclampsia was determined to be an other important medical event. Other business partners included are: E2008-00543. No further information expected.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 20Aug07)

Prex Vax Illns:

Vaers Id: 357777-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-Jun-2009	21-Jul-2009	49	21-Sep-2009	01-Oct-2009	FL		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	000000	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Alopecia, Emotional disorder, Fatigue, Pruritus, Scab

Symptom Text: Patient had her second injection of the Gardasil Shot in June 2009 and since then she has lost most of her hair. She is also getting scabs on her head also and itching. She is fatigued and very emotional. She continues to miss days at school because of the humiliation she faces at school with the loss of her hair.

Other Meds: None

Lab Data: She has had blood test to see if it is Thyroid and the test was well within the standards and the only other thing she has done different is this vaccination that she did not want to begin with. Her Doctor and her father insisted she have

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 357787-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Aug-2009	11-Aug-2009	0	21-Sep-2009	01-Oct-2009	WI		02-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2818AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B039AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Concussion, Erythema, Fall, Head injury, Hyperhidrosis, Nausea, Syncope, Unresponsive to stimuli

Symptom Text: Pt was given 3 immunizations and was being instructed by MA to remain seated when pt had an episode of vasovagal syncope and fell off exam table and onto floor. She did strike her head. Pt was noted to be unresponsive for no more than several seconds by MA. Dr. was called into room immediately and found pt responsive at that time, breathing, with good color, and sitting on floor. Pt was lifted to table with assist of 3 staff and found to be diaphoretic and nauseated but did not vomit. Pt showed no focal neurologic signs. She did have mild erythema over the forehead, otherwise no head or facial swelling. On physical assessment, no other signs were noted and pt was following commands. Pt was observed for approx 10-15 minutes prior to being sent for head CT, which was negative for skull fx or internal head injury. Pt mother was advised by Dr. that pt sustained a concussion from the fall, and pt may c/o HA for a week or so. Pt mother advised to call if any change in pt condition or onset of new symptoms. Pt was observed in clinic setting for total of about 2 hours prior to leaving.

Other Meds: none

Lab Data: Head CT

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 357797-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Jul-2008	15-Oct-2008	97	21-Sep-2009	30-Sep-2009	TX		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2580AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Autoimmune thyroiditis, Epstein-Barr virus infection, Fatigue, Goitre, Headache, Hypersensitivity, Hypothyroidism, Infectious mononucleosis, Insomnia, Menorrhagia, Menstrual disorder, Myalgia, Pharyngitis streptococcal, Sensation of heaviness, Swelling, Swelling face, Weight increased

Symptom Text: extreme fatigue, mono, chronic strep throat, Hashimoto's, extreme face and body swelling, aching muscles. Got first vaccine 7/10/09 Lot 0072X in conjunction with Menactra vaccine. Second vaccine 12/22/08 Lot 1311X. Went to college on cross country scholarship. Started off season great. She said she started noticing that she was having trouble running mid October and that her legs felt heavy. Starting getting facial swelling second week of January. Went to doctor and they said it was allergic reaction. Got sick in February - dx with strep. Didn't get better. Went to ER end of March with extreme facial swelling. Told her it was allergy and gave her prednisone. Re-dx with strep again in early April and then mono April 9th. Got really sick and could not get better. Extreme facial and body swelling. Dx with Hashimoto's June 29th. and started thyroid treatment. Was not able to return to college in August and is still home. Started getting muscle soreness in July. Made Gardasil connection 2 weeks ago and is going to begin treatment by doctor who has helped several other gardasil patients. 10/13/09 Medical records received, Dates of Service 4/19/09-8/10/09. Dx: Other Specified Acquired Hypothyroidism, Abnormal Weight Gain, Oligomenorrhea, Fatigue, Thyromegaly. Presenting Sx: Pt. experienced an approximately 40 lb. weight gain over a 1 to 2 month period, additionally she c/o fatigue, trouble sleeping and staying asleep, facial swelling, swelling around eyes, acne, one terminal hair periumbilical, headaches and a heavy period. Pt. saw a nutritionist and was put on a diet plan. She experienced menarche at age 13 and had irregular periods for several years (approximately 6 periods/yr.). Ortho Tri-Cyclene-Low was initiated which she took for several years, but stopped early this year after missing several pills. She re-started the pill a few months ago. Concomitantly, she takes Synthroid, Cosyntropin and furosemide. She was diagnosed with mononucleosis in April, and tested positive for Epstein-Barr Virus in May. H

Other Meds: none

Lab Data: mono - April 9, 2009 and June 30, 2009. Two Positive strep tests. Tested positive Hashimoto's - 6/30/2009. Thyroid Uptake and ultrasound confirmed thyroid on low side of normal -nothing accounted for extreme symptoms she was experiencing.

History: Ortho-tryclen Low. 10/13/09 Medical records received, Dates of Service 4/19/09-8/10/09. PMH: Streptococcal infection 4/9/09, ear infections, mononucleosis 4/12/09, Allergic to Penicillin.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357890-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	10-Sep-2009	11-Sep-2009	1	22-Sep-2009	02-Oct-2009	IN		02-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB311AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0806Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0216Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Injection site erythema, Injection site pain, Injection site swelling, Pyrexia, Urticaria

Symptom Text: 9-11-09 off @ 2:30p (showing swelling/reddness) tired + in pain @ location. At midnight fever/hives. Visited ER @ 9:30AM 9-12-09. Tx with KEFLEX.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 357906-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Jun-2009	29-Jun-2009	0	22-Sep-2009	23-Sep-2009	FR	WAES0909USA01933	23-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0772X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness transient, Malaise, Nausea, Syncope

Symptom Text: Information has been received from the Health Authority concerning a 25 year old female with no history of adverse reaction to any drug, who on 29-JUN-2009 was vaccinated with her first dose of GARDASIL (lot # 0772X, Batch # NK13910/0772X). IM. Concomitant therapy included hormonal contraceptives (unspecified). Ten minutes after the vaccination, the patient experienced general malaise defined by nausea, fainting and temporary vision loss. Approximately 24 hours later, the event regressed and the vital signs stabilized. At the time of the report, the patient had recovered. Health Authorities considered the case as other medically important condition. Other business partner numbers included E2009-08678.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 357908-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Sep-2009	15-Sep-2009	0	22-Sep-2009	23-Sep-2009	CA	WAES0909USA02188	23-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	2	Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Immunisation reaction, Lymphadenopathy, Nausea, No reaction on previous exposure to drug, Throat tightness, Vomiting

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female with no medical history or drugs allergies, who on 02-JUL-2008 was vaccinated with a 0.5 mL first dose of GARDASIL (lot # 660555/0279X), intramuscularly. The patient received a second dose of GARDASIL vaccine (lot 660612/0229X) on 03-SEP-2008 and a third dose of GARDASIL vaccine (lot # 661046/0381X) on 15-SEP-2009. There was no concomitant medication. The patient experienced reactions after her third dose of GARDASIL vaccine. The patient had vomiting, nauseas, and swollen glands. Her throat tightened also. The patient did not have any reactions from the first and the second doses of GARDASIL vaccine. No laboratories studies performed. The patient went to an emergency room but recovered within 10 minutes. A lot check has been initiated. Throat tightened was considered to be immediately life-threatening. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357909-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		22-Sep-2009	23-Sep-2009	FR	WAES0909USA02217	23-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Leukopenia, Pyrexia

Symptom Text: Information has been received from a pediatrician concerning a 13 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (lot #, injection site and route not reported). 14 days post vaccination the patient experienced fever and leucopenia (1500 leukocytes/microl) and was admitted to hospital. Meningism was excluded. Thoracic x-ray showed a doubtful result and antibiotics were given. The patient improved under this treatment. At the time of reporting the patient was discharged with a value of 300 leukocytes/microl. Other business partner numbers included E2009-08694. No further information is available.

Other Meds: Unknown

Lab Data: chest X-ray, showed a doubtful result; WBC count, 1500 /microl, 14 days post vaccination; WBC count, 3000/microl, discharge

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357919-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Aug-2009	Unknown		22-Sep-2009	22-Oct-2009	CA		17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Chest pain, Dyspnoea, Eye pain, Headache, Heart rate increased, Hypoaesthesia, Pallor, Urticaria

Symptom Text: Chest pain, trouble breathing, rapid heart beat, abdominal pain, numbness in leg, numbness in jaw, sweating, paleness, headaches, numbness in arm/hand, hives. 12/4/2009 PCP records for visits 5/2009-11/2009. Patient with c/o's headaches, eye pain, per patient went to ED 9/2009 with same c/o's and a neg w/up, no tx noted

Other Meds:

Lab Data: Labs: CBC, CMP, UA w/culture normal, abnormal pap smear Dx studies: MRI Head wnl

History: PMH: None Allergies: NKDA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357925-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	19-Aug-2009	21-Aug-2009	2	22-Sep-2009	02-Oct-2009	FR		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	
	ANTH	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mass, Pruritus

Symptom Text: Approximately 2 days post vaccination developed small itchy bump on (L) arm and spread to (R) arm, back and both legs.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **357933-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Aug-2009	28-Aug-2009	0	22-Sep-2009	23-Sep-2009	FR	B0593589A	23-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TD	GLAXOSMITHKLINE BIOLOGICALS	XC12B018L1		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NJ26310		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Syncope, Tonic clonic movements

Symptom Text: This case was reported by a regulatory authority and descried the occurrence of vasovagal syncope in a 14-year-old female subject who was vaccinated with DITANRIX adult (GlaxoSmithKline), (non-GSK) GARDASIL. The subject's medical history included syncope without loss of consciousness. On 28 August 2009 the subject received unspecified dose of DIANRIX adult (intramuscular), unspecified dose of GARDASIL (intramuscular). On 28 August 2009, immediately after vaccination with DITANRIX adult and GARDASIL, the subject experienced vasovagal syncope with loss of consciousness lasting 1 minute and tonic clonic movements lasting seconds. The regulatory authority reported that the events were clinically significant (or requiring intervention). Relevant test included normal blood glucose, normal neurological examination as well as electrocardiogram. On 28 August 2009, the subject recovered spontaneously. The vaccination course with DITANRIX adult was discontinued. The regulatory authority reported that the events were possibly related to vaccination with DITANRIX adult and GARDASIL. No further information was available as this was all the information that regulatory authorities had.

Other Meds:

Lab Data: Blood glucose, normal; Electrocardiogram, normal; Neurological examination, normal

History: SYNCOPE

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **357937-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Sep-2009	04-Sep-2009	1	22-Sep-2009	02-Oct-2009	MI		23-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0650X	0	Right leg	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB239AA	0	Left leg	Intramuscular	
MNQ	SANOFI PASTEUR	U2826CA	0	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug hypersensitivity, Pyrexia, Rash erythematous, Rash pruritic, Swelling

Symptom Text: Child woke today with low grade fever 100 degrees and red/raised rash on her truck (back, shoulder blades, abd). Rash is itchy. Mom treating with TYLENOL, BENADRYL and Oatmeal Bath. Hx of allergy to PENICILLIN - BACTRIN.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **358009-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-May-2008	09-Feb-2009	271	22-Sep-2009	28-Sep-2009	SC		03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1987U	3	Left arm	Unknown	FLU

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Dyspnoea, Fatigue, Gallbladder disorder, Gallbladder operation, Headache, Hyperhidrosis, Hypoglycaemia, Nausea, Oropharyngeal pain, Pyrexia, Sinusitis, Type 1 diabetes mellitus, Vomiting

Symptom Text: Shortly after taking the vaccine she developed type I juvenile diabetes and also later had to have her gall bladder removed because it was not functioning properly. She was perfectly healthy until recieving the vaccine. She is now on an insulin pump for the diabetes. ```12/2/09 Primary care records received for dates of service 5/14/08 Dx: Diabetes Mellitus Type 1, sinusitus, Abdominal pain, epigastric. Vomiting. 2/12/09 Presents with moderate fatigue, no weight loss, good appetite, checking blood sugar QID. Has had 1 hypoglycemic episode, scheduled for endocrinology consult and diabetes education. 4/20/09 Uncontrolled sugars up and down, frequent episodes of hypoglycemia. 5/1/09 C/o Nausea, low grade fever, HA, Sugars up. 5/18/09 C/o Sore throat, HA, cough, Dx: sinusitus. 7/23/09 C/o Abdominal pain. Dx: Abdominal pain epigastric. 9/8/09 C/o vomiting, HA, diaphoresis, SOB. Dx: Vomiting, abdominal pain, epigastric.

Other Meds:

Lab Data: ```12/2/09 Primary care records received for dates of service 5/14/08 Labs and diagnostics: Glucose 153.

History: None. ```12/2/09 Primary care records received for dates of service 5/14/08. PMH: ADD, Migraine HA, Acne.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **358014-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	16-Jul-2009	26-Aug-2009	41	23-Sep-2009	30-Sep-2009	CA		07-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Faeces discoloured, Gastritis, Hepatic enzyme abnormal, Nausea, Pyrexia

Symptom Text: Liver enzymes were elevated. On the day of the vaccination (7/16/09), ALT was recorded at 17. On 08/26/09, ALT was recorded at 130. On 9/4/09, ALT was recorded at 158. On 9/11/09, ALT was recorded at 117. Ultrasound of the liver was performed on 9/16/09 with results pending. 8/5/09 PCP medical records service dates 716/09 to 9/11/09. Assessment: Gastritis Patient presented with abdominal pain, black stools, fever, nausea. Dizziness.

Other Meds: n/a

Lab Data: On the day of the vaccination (7/16/09), ALT was recorded at 17. On 08/26/09, ALT was recorded at 130. On 9/4/09, ALT was recorded at 158. On 9/11/09, ALT was recorded at 117. 8/5/09 PCP medical records service dates 716/09 to 9/11/09. LA

History: n/a

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358040-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Sep-2009	14-Sep-2009	0	22-Sep-2009	22-Oct-2009	TX		22-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2919AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	00874	1	Right arm	Unknown	
	FLU	SANOFI PASTEUR	U317615A	3	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Skin laceration, Syncope

Symptom Text: Given MENACTRA, GARDASIL, Influenza Vaccines. Approximately one minute after administration, adolescent, while sitting down, had syncopal episode, landed face first on floor braking glasses causing 2 lacerations to right eye between eyebrow & eyelid.

Other Meds: ALBUTEROL; MDI; SINGULAIR

Lab Data: Eye exam + stitches

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358046-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Aug-2009	Unknown		22-Sep-2009	22-Oct-2009	--		22-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2914AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness

Symptom Text: Weak, dizzy x 5 days.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358049-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Jul-2009	28-Jul-2009	0	22-Sep-2009	22-Oct-2009	NY		22-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2670AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Blood pressure increased, Cold sweat, Feeling cold, Heart rate decreased, Heart rate normal, Pallor

Symptom Text: Pt became weal after receiving HPV injection and was assisted to supine position on examining table. Immediately reported feeling better. Recommended meningitis be with held today. Pt and mother stated pt. needs meningitis for college. Requested immunization today. Meningitis given. Pt then became weak and pale. No improvement. Pt became cold, clammy c/o abd. pain. 911 called. Pt declined stated going to her own private MD. Ambulated out of clinic assisted by her mother. Initial B/P 150/98 P 60 T 96.7 when paramedics arrived B/P 110/59 P 56.

Other Meds:

Lab Data:

History: Seasonal allergies

Prex Illness: none

Prex Vax Illns:

Vaers Id: **358084-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	25-Sep-2008	25-Sep-2008	0	23-Sep-2009	24-Sep-2009	FL	WAES0908USA03808	01-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acne, Adenoiditis, Bronchitis, Dehydration, Haematuria, Hypertension, Inappropriate schedule of drug administration, Iron deficiency anaemia, Migraine, No reaction on previous exposure to drug, Palpitations, Tonsillitis, Xanthelasma

Symptom Text: Information has been received from a certified medical assistant concerning a 29 year old female who on 25-SEP-2008 was vaccinated with a first dose of GARDASIL. The patient developed high blood pressure. The patient had always had normal blood pressure. Her blood pressure on 02-OCT-2008 was 148/88 and on 06-JAN-2009 it was 158/98. The patient sought unspecified medical attention. The patient's outcome is unknown. Follow up information received on 14-SEP-2009 from a physician indicated that the patient was a 28 year old female with no medical history, allergies or illness at the time of vaccination; it was also reported that the patient did not experience any adverse events following prior vaccinations. On 25-SEP-2008 at 10:15 was vaccinated with the first dose of GARDASIL (lot # 661764/0650X), intramuscularly. The patient received a second dose of GARDASIL (lot # 661764/0650X), intramuscularly on 20-NOV-2008 at 10:00. In October 2008, after the 2 doses of GARDASIL the patient developed high blood pressure. The patient was treated with hypertensive medication. The patient had an electrocardiogram done. At the time of this report the patient had not recovered. High blood pressure was considered to be an other important medical event. No further information is available. 9/30/09 Received PCP medical records of 6/30/09- Records reveal patient was new patient to practice on 6/30 for essential hypertension management & had palpitations, microscopic hematuria, migraines, iron def anemia & acne. Work up had been done be another MD. Exam revealed xanthelasma. BCPs had been d/c for 1 wk. Advised against restarting & was also advised to d/c all meds due to probable drug induced HTN. RTC 8/6/09 w/fever, cold s/s, enlarged & tender cervical lymph nodes. Dx w/chronic tonsillitis & adnoiditis, dehydration. Tx w/oral antibiotics. Did not improve & RTC 8/13/09 w/wheezing & SOB. Dx w/acute bronchitis. Tx w/steroids, nebs, continued antibiotics & cough syrup. RTC 9/10 w/continued HTN, restarted on anti-HTN meds &

Other Meds: Unknown

Lab Data: blood pressure, 10/02/08, 148/8; blood pressure, 01/06/09, 158/9 9/30/09 Received medical records w/LABS: EKG. Vit B, oleic acid & antioxidant deficiencies.

History: Unknown 9/30/09 Medical records received w/PMH: seasonal allergies, pollen, hayfever.

Prex Illness:

Prex Vax Illns:

Vaers Id: **358085-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	31-Oct-2008	31-Oct-2008	0	23-Sep-2009	24-Sep-2009	KS	WAES0909USA02430	24-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a office manager, for GARDASIL, a Pregnancy Registry Product, concerning a 23 year old female who on 11-SEP-2008 was vaccinated with the first dose of GARDASIL (0.5ml, IM). On 31-OCT-2008 the patient received the second dose of GARDASIL (0.5ml, IM, lot# 659653/1448U). Concomitant therapy included omeprazole and DIFLUCAN. Subsequently the patient got pregnant on an unspecified date. In April 2009, the baby girl was born prematurely and was on an incubator. The patient had a 2 month postpartum visit on 30-JUN-2009. A physician had a note in a chart saying the third dose of GARDASIL would hold off since the patient was breastfeeding. At the reporting time the outcome was unknown. Additional information has been requested.

Other Meds: DIFLUCAN; omeprazole

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358096-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	03-Sep-2009	03-Sep-2009	0	23-Sep-2009	05-Oct-2009	NY		05-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: After administering the vaccine, pt complained of feeling lightheaded and passed out. Pt responded immediately to smelling salts, was alert and oriented X 3, vital signs stable. Pt reported she "forgot" to mention she has felt light headed after injections and her mother and sister have fainted just after injections.

Other Meds: LO OVRAL

Lab Data: None

History: Patient reports allergy to cold medicine and environmental.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358125-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Sep-2009	Unknown		23-Sep-2009	05-Oct-2009	CO		05-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	500687P	0	Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C27773AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Pt was asked if there was any chance she could be pregnant due to late menses. She replied, "No, my periods are always funky." During visit, HCG was done and it was positive for pregnancy. So far, no known adverse reactions.

Other Meds: none

Lab Data: HCG Positive

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **358126-1** **Related reports:** 358126-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Sep-2009	23-Sep-2009	0	23-Sep-2009	30-Sep-2009	CA		19-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0053X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysmenorrhoea, Loss of consciousness, Postictal state, Presyncope, Tonic clonic movements

Symptom Text: Patient with history of chilhood seizure. Seizure free since 4 years of age. Patient had vaso-vagal episode briefly lost consciousness and had 5 to 6 seconds of clonic-tonic jerking arms and legs. Patient had post-ictal state for 2 hrs. 10/05/09 Received PCP medical records which included Neuro consults of 1998. FINAL DX: Generalized tonic seizure disorder. Records reveal that patient initially experienced night time seizure activity 4/98 followed by vomiting x 1 w/congestion & cough but no fever. Dx w/bronchitis & tx w/antibiotics. After 2nd abnormal EEG, started on antiseizure meds & did well. 10/6/09 Received Neuro medical records of 10/2/09. FINAL DX: syncopal attacks, likely vagal; hx of generalized seizrue disorder in childhood, treated & idiopathic; dysmenorrhea. Referred for EEG & if abnormal, an MRI. No further medical records available.

Other Meds: none

Lab Data: N/A 10/5/09 Medical records received w/LABS: EEG abnormal.

History: Seizure disorder (seizure free for 12 years)

Prex Illness: none

Prex Vax Illns:

Vaers Id: **358126-2** **Related reports:** 358126-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Sep-2009	23-Sep-2009	0	29-Sep-2009	30-Sep-2009	CA	WAES0909USA03753	30-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0053X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Electroencephalogram, Grand mal convulsion, Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning a 15 year old female with a history of seizures and no known drug allergies who on 23-SEP-2009 was vaccinated with a first dose of GARDASIL (injection, lot# 0053X). There was no concomitant medication. No other vaccine was given on that day. On 23-SEP-2009, the patient experienced syncope and tonic-clonic seizure activity approximately 1 minute after receiving her first dose of GARDASIL. The patient was out for 5-6 seconds. The patient got an electroencephalography (EEG) and saw her previous neurologist. At the time of the report, the patient was recovering. Upon internal review, tonic-clonic seizure activity was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vaers Id: 358135-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Aug-2009	05-Sep-2009	16	23-Sep-2009	30-Sep-2009	OK		21-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Chest discomfort, Constipation, Dysphagia, Dyspnoea, Faecaloma, Injection site induration, Injection site pain, Injection site urticaria, Menstruation irregular, Oropharyngeal pain, Rash, Urticaria, Vaccine positive rechallenge

Symptom Text: 2ND HPV VACCINE GIVEN ON 4/2/09. ON 7/9/09 CLIENT HAD HIVES FROM HEAD TO TOE INCLUDING ARMS, LEGS, AND TRUNK. HIVES ALSO INSIDE HER MOUTH. SHE WENT TO E.R. AND RECEIVED A CORTISONE INJECTION. ETIOLOGY OF THE HIVES UNKNOWN BY PHYSICIAN. ON 7/10/09 SHE SEEN PCP WHO OBTAINED LAB WORK AND MEDROL DOSE PACKET PRESCRIBED BUT CLIENT WAS UNABLE TO SWALLOW PILLS. 7/11/09 WENT TO E.R. R/T HIVES TO LIPS AND MOUTH AND PT. WAS HAVING DIFFICULTY BREATHING FEELING TIGHTNESS TO CHEST. SHE WAS GIVEN EPINEPHRINE AT THE E.R.-THEN ALL SYMPTOMS RESOLVED WITHIN 48 HOURS. THEN ON 8/20/09 CLIENT RECEIVED HER 3RD HPV INJECTION. ON 9/5/09 CLIENT EXPERIENCED LOWER RT. ABDOMINAL PAIN AND BLOATING. ALSO HAD 3 MENSES IN 9/09 AND REPORTS IS USUALLY REGULAR WITH MENSES OCCURRING EVERY 28-30 DAYS. THE 2ND WEEK OF SEPT./09 SHE WENT TO CARE AND SEEN PHYSICIAN WHO ORDERED AN ABDOMINAL CT SCAN SHOWING FECAL IMPACTION. THE CLIENT TOOK MAGCITRATE WITHOUT RESULTS. CLIENT STATES SHE NORMALLY HAS REGULAR BOWEL MOVEMENTS. HER ABDOMINAL PAIN CONTINUED EVEN AFTER HAVING A BOWEL MOVEMENTS. TWO DAYS LATER SHE WENT TO URGENT CARE AND HAD LAB OBTAINED TESTING HER URINE AND BLOOD WHICH SHE REPORTS CAME BACK NORMAL. SHE REPORTS THE SEVERE ABDOMINAL PAIN CONTINUED. ON 9/22/09 CLIENT COMPLAINED OF LT. ARM PAIN AT THE HPV INJECTION SITE AND HAVING 1 SMALL HIVE AT THE INJECTION SITE WHICH WAS NOTICED BY HER MOTHER-LATER IN THE DAY THERE WAS A RAISED INDURATION GREATER THAN 1CM PALPATED AT THE INJECTION SITE. CLIENT ALSO REPORTS ON 9/22/09 HAVING A RASH TO BOTH UPPER THIGHS, TIGHTNESS IN HER CHEST, AND DIFFICULTY BREATHING. CLIENT PLANS TO FOLLOW-UP WITH HER PCP AND WILL REQUEST AN ABDOMINAL ULTRA SOUND. 9/28/09 Urgent care records received DOS 9/16/09. Assessment: Abdominal pain, constipation. Patient presents with abdominal pain of one week duration. 10/19/09 Primary care records received for dates of service 8/28/97 to 7/9/09 Assessment: Seen for hives on 7/9/09. Right lower abdominal pain and sore throat on 9/25/09.

Other Meds: NO

Lab Data: URINE AND BLOOD TESTING DONE WAS NORMAL. ABDOMINAL CT SCAN SHOWED FECAL IMPACTION. 9/28/09 Urgent care records received DOS 9/16/09. LABS and DIAGNOSTICS: CT Scan - feces noted. CBC - Eosin 7.5% (H) Eosin 0.7 T/CMM (H). CHEM - ALP 66 U/L

History: NO. 10/19/09 Primary care records received for dates of service 8/28/97 to 7/9/09. PMH: None.

Prex Illness: NO

Prex Vax Illns:

Vaers Id: 358211-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Dec-2008	18-Jun-2009	189	24-Sep-2009	25-Sep-2009	NC	WAES0909USA02180	21-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB291CA	1	Unknown	Unknown	HEPA
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Intramuscular	HPV4
	FLU	SANOFI PASTEUR	U2083AA		Unknown	Unknown	MNQ

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anticoagulant therapy, Back pain, Chest pain, Oral contraception, Pain, Painful respiration, Pulmonary embolism

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female patient with pertinent medical history reported as none and drug reactions or allergies reported as none who on 02-JUN-2008 was vaccinated with a first dose of GARDASIL. On 31-JUL-2008 she received a second dose of GARDASIL (lot #660553/0070X). On 11-DEC-2008 she received third dose of GARDASIL (lot #660553/0070X). Concomitant therapy included hormonal contraceptives (unspecified). On 18-JUN-2009, the patient went to the emergency room with a pulmonary embolism and was admitted to the hospital. The patient had been placed on COUMADIN. On an unspecified date the patient recovered from the pulmonary embolism (PE). Follow up information has been received via telephone call from a licensed practical nurse who reported that on an unspecified date, the patient was placed on oral contraceptive (name not available) for heavy menses. On 02-JUN-2008 the patient received HAVRIX (unspecified) (lot # AHAVB264CA) and MENACTRA (lot # U2623AA) in addition to first dose of GARDASIL. On 31-JUL-2008 no other vaccines were given. On 11-DEC-2008 she received HAVRIX (unspecified) (lot # AHAVB291CA) and FLUZONE (lot # U2083AA) in addition to third dose of GARDASIL. On 18-JUN-2009 the patient presented to the emergency room with chest and back pain. Chest computed axial tomography showed multiple PEs in both lower lobes and the patient was hospitalized. The patient was started on heparin drip, oral contraceptive was discontinued (patient told never to resume it again); switched from heparin to LOVENOX injections. On 22-JUN-2009 the patient was discharged, the patient was placed on oral COUMADIN. At the time of discharge the patient was able to resume all previous activities. Chart did not show if the event was considered life threatening. No further information is available. 9/29/09 ER records received DOS 6/18/09. Assessment: R/O Pulmonary Embolism. Patient presents with sharp pains (L) rib area midside up to (L) shoulder. Worsens with deep bre

Other Meds: hormonal contraceptives. 9/29/09 ER records received DOS 6/18/09. Tubes in ears.

Lab Data: chest computed axial 06/18?/09, multiple PEs in both lower lobes. 9/29/09 ER records received DOS 6/18/09. LABS and DIAGNOSTICS: CBC - RBC 4.07 X10^3/UL (L) RDW 11.3% (L) GR 64.6% (H) LY 2.4% (L) MO 10.2% (H). CHEM - Chloride 109 MMOL/L (

History: PMH: Tubes in ears. 12/10/09 Medical records received w/PMH: NKDA;heavy menses, on birth control pills.

Prex Illness: Heavy periods

Prex Vax Illns:

Vaers Id: 358212-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2009	05-Jul-2009	4	24-Sep-2009	25-Sep-2009	MO	WAES0909USA01991	05-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	1	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB238AA	1	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Arthralgia, Contusion, Drug hypersensitivity, Dysuria, Haematuria, Headache, Heart rate increased, Nausea, Pain in extremity, Petechiae, Purpura, Pyrexia, Rash, Rash maculo-papular, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a registered nurse and an office administrator concerning the nurse's 16 year old daughter with no pertinent history who on 01-JUL-2009 was vaccinated with the first dose of GARDASIL (Lot # 658271/0558X). Concomitant therapy include HAVRIX (unspecified) (lot# AHAVB238AA) with the first dose of GARDASIL. On 05-JUL-2009 the patient went to the emergency room with nausea, vomiting, fever, severe stomach pains and headaches. On 08-JUL-2009 the consumer called the office complaining of joint pain and ibuprofen was recommended. On 09-JUL-2009 the the consumer called the office again with complaint of increased joint pain It was reported that the patient could still eat food, but on 18-JUL-2009 the patient went to the emergency room since what she was experiencing was not getting better. The registered nurse also reported that the patient was admitted to hospital. At the hospital the patient was given fluids in case it was her kidney and also drew blood. The patient was also given SEPTRA which caused her to have tiny bruises on top of her two thighs. The registered reported that the patient was in the hospital for four days and was doing better after that. Then on 05-SEP-2009, the patient received her second dose of GARDASIL (Lot# 662404/0312Y) and then on 15-SEP-2009 (also reported as 11-SEP-2009) the patient started to experience severe stomach pains, nausea, vomiting, fever and headaches. No complaints of joint pain at that time. Therapy with GARDASIL was discontinued. The results of blood work were unknown. The registered nurse reported that they had called her physician, but the patient had not yet recovered. This is one of several reports from the same source. Additional information has been requested. 9/30/09 Hospital records, DC summary, received DOS 7/5/09 to 7/8/09. Assessment: Febrile illness, purpuric rash, maculopapular rash. Patient presents with a 3 day history of crampy abdominal pain aggravated by urination. Dysuria, vomiting, and hematuria. Red rash abdomen and

Other Meds:

Lab Data: diagnostic laboratory. PMH: CBC - WBC 1.7 K/uL (L) MCV 78.9 fL (L) MCH 26.8 pg (L) Platelet 121 K/uL (L) Bands 21% (H) Neutro 1.2 K/uL (L) Lymph 0.3 K/uL (L). Urinalysis - Hazy, Leukocyte Esterase trace, Protein 1+, Ketones 2+, Urobilinogen

History: None. Urine Culture (+). Tick bites. Tosillectomy.

Prex Illness: UTI, given Septra day prior to vaccination.

Prex Vax Illns:

Vaers Id: **358213-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Jul-2007	01-Feb-2009	571	24-Sep-2009	25-Sep-2009	--	WAES0909USA02796	25-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female patient who on 17-JAN-2007 was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (Lot# was unknown). On 16-MAR-2007 the patient was vaccinated intramuscularly with the second 0.5 mL dose of GARDASIL (Lot# was unknown) and on 11-JUL-2007 the patient was vaccinated intramuscularly with the third 0.5 mL dose of GARDASIL (Lot# was unknown). In February 2009, the patient started developing a seizure disorder. The patient sought medical attention by specialist visit. At the time of the report, the patient's seizure disorder persisted. Upon internal review, seizure disorder was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358229-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	17-Jul-2009	18-Jul-2009	1	24-Sep-2009	27-Oct-2009	NY		27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294Y		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Oropharyngeal blistering, Pyrexia, Vomiting

Symptom Text: The day after receiving GARDASIL patient experienced fever of 103 degrees F for three days. Nausea, vomiting, blisters on tongue.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358237-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Sep-2009	24-Sep-2009	1	24-Sep-2009	23-Oct-2009	LA		23-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	500688P		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0229X		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea

Symptom Text: Thursday, Sept. 24, 2009 at or about 1:20 p.m. a telephone call was received at clinic from the mother of patient stating the patient was complaining of difficulty breathing since FluMist administration. Instructed parent to take patient to the nearest emergency room for further evaluation.

Other Meds:

Lab Data:

History: Penicillin

Prex Illness:

Prex Vax Illns:

Vaers Id: 358271-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Aug-2009	19-Aug-2009	1	24-Sep-2009	29-Sep-2009	CA		20-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0670Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Cyst, Deafness neurosensory, Dizziness, Ear discomfort, Headache, Nausea, Steroid therapy, Tinnitus

Symptom Text: headache day of injection 8/18, ear discomfort and sudden hearing loss 8/19 to R ear. appointment with PCP 8/20. appt with ENT specialist 8/24, prescribed prednisone. appointment with audiologist 8/24. apointment with ENT specialist and Audiologist 9/8. MRI ordered and done 9/10. appt 9/11 with ENT specialist for steroid injection to R ear. Appt 9/22 with ENT specialist and audiologist. labs ordered. 9/28/09 ENT Consultant records DOS 8/24/09 DOS 8/24/09 to 9/27/09. Assessment: Sensorineural Hearing Loss. Patient c/o decreased hearing (R) ear, dizziness. Profound sensorineural hearing loss (R) ear, normal hearing (L) ear. Tinnitus. Nausea. Left maxillary sinus bone mucous retention cyst 12/30/09 Pediatric Medical records received for DOS 08/24/09, 09/15/09. Telephone request for referral to ENT specialist. On prednisone and will f/u with ENT Impression : viral hearing loss, probably not vaccine related.. ```1/14/10: Summary of ENT visits received for dates of service 8/24/09 to 10/30/09. Dx: Profound sensiorineural hearing loss in R ear. Treated with prednisone with no change. Unchanged audiogram, normal tympanograms, MRI normal. No improvement after intratympanic decadron.

Other Meds:

Lab Data: MRI IAC: normal. labs: ESR, ANA SCREEN, COMPREHENSIVE METABOLIC PANAL: pending. 9/28/09 ENT Consultant records DOS 8/24/09 LABS and DIAGNOSTICS: Audiogram - Abnormal. MRI - Abnormal. ANA - Pending. Chem - WNL. ```1/14/10: Summary of ENT

History: none. 9/28/09 ENT Consultant records DOS 8/24/09. Asthma.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **358273-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Sep-2009	22-Sep-2009	14	24-Sep-2009	30-Sep-2009	FL		09-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3211AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blindness transient, Dizziness, Dysarthria, Headache, Hypermetropia, Hypoaesthesia, Hypoaesthesia facial, Migraine, Myodesopsia, Nausea, Oral contraception, Paraesthesia, Vision blurred

Symptom Text: Headache, then blurry vision, numbness in right hand the right side of the face, numbness on right side of the body. Slurred speech. No treatment. Blurred vision lasted 5 minutes,numbness went away in about 1 hour. 10/6/09 PCP medical records neuro and ophth consults DOS 2/17/09 to 9/22/09. Assessment: Transient visual loss, headache, migraine, hyperopia. Patient presents with blurred vision, floaters. Tingling in hand, shoulder, facial area, down leg, felt that she would pass out. Lightheaded, nauseous. Numbness right side. Oral contraceptives.

Other Meds: birth control

Lab Data: Primary care doctor visit the same day. Visited Neurologist the next day. Eye doctor 2nd day and had a MRI and MRA.

History: Headaches. 10/6/09 PCP medical records neuro and ophth consults DOS 2/17/09 to 9/22/09. Chronic headaches with photophobia. Lightheaded. CT Brain - Maxillary sinus changes. MRI Brain - Abnormal, consistent with migraines, cerebellar tonsillar ectopy, right maxillary sinusitus. Stomach aches, knee pain, growing pains. Right shoulder lower than left. Moody, labile, angry spells. Mens

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358275-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-May-2009	Unknown		24-Sep-2009	30-Sep-2009	KS		21-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Acute sinusitis, Adverse drug reaction, Arthralgia, Asthenia, Confusional state, Decreased appetite, Dehydration, Depression, Diarrhoea, Eye disorder, Faecaloma, Headache, Hypoaesthesia, Hypoaesthesia oral, Labyrinthitis, Malaise, Neurological examination normal, Panic attack, Paraesthesia, Pharyngeal erythema, Pharyngitis, Rash, Rash erythematous, Rash papular, Rash pruritic, Streptococcal infection, Tonsillitis, Vomiting

Symptom Text: since 8/6/09 pt has had headaches, eye problems, confusion, numbeness in hands and feet. Had MRI that was negative, bones are achey. Pt had Strep at the end of July, vomiting with amoxicillin then inner ear infection in august.10/19/09. 10/05/09 Neurology consult received DOS 9/22/09. Assessment: Panic attacks. Patient was first noted to have red itchy bumps on arms and abdomen. The bumps eventually went away. Throat was red, placed on amoxicillin and started to vomit. Found to have urinary tract infection, placed on antibiotic and vomited again. Inner ear infection, placed on antibiotics, vomited, could not eat. Became confused and was seen at an ER where she had a panic attack followed by perioral numbness along with numbness and tingling of hands and feet. Fecal retention, ER visit, panic attacks. Patient now to be evaluated for c/o paresthesias over hands / feet , malaise, arthralgia. Neurological exam normal.Primary care and emergency department records received for dates of service 8/7/09 to 9/22/09. Dx: Streptococcal pharyngitis on 8/7/09. Vomiting, diarrhea, dehydration, tonsillitis 8/11/09. Acute sinusitus 9/4/09. Abdominal pain, vomiting in ED 9/6/09. Weakness, constipation, chills, numbness 9/8/09. Weakness, depression with anxiety, numbness and abdominal pain 9/9/09. Anxiety, vomiting in ED 9/10/09.

Other Meds:

Lab Data: saw neurologist Dr Kumar He told mother and pt that it was a reaction from Gardasil. LABS and DIAGNOSTICS: MRI Brain - Arachnoid cyst an incidental finding. CT Scan Head - Normal. X-ray Abdominal Series - Abnormal. 10/19/09 Primary care and

History: Primary care and emergency department records received for dates of service 8/7/09 to 9/22/09. PMH: None.

Prex Illness:

Prex Vax Illns:

Vaers Id: **358295-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Sep-2009	21-Sep-2009	0	24-Sep-2009	30-Sep-2009	IN		12-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB327AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0672Y	0	Left arm	Intramuscular	
IPV	SANOFI PASTEUR	A1109-2	0	Right arm	Subcutaneously	
MMR	MERCK & CO. INC.	0449Y	0	Right arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U3012AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041BA	0	Right arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB730AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0999Y	0	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Cold sweat, Convulsion, Dyskinesia, Gaze palsy, Immediate post-injection reaction, Lethargy, Musculoskeletal stiffness, Opisthotonus, Pallor, Posturing, Syncope, Unresponsive to stimuli

Symptom Text: Immediately after receiving vaccinations, patient arched back, neck extended back and to the right, eyes fluttered and rolled back. Patient not responsive; not answering questions or talking. She was eased from the chair to the floor. Her body was stiff and jerking and had to be fully supported by 2 individuals. The jerking stopped within 2 minutes. Patient remained lethargic, eyes opened and then slowly closed repeatedly for the next ~15 minutes. Patient complained of upset stomach immediately following seizure-like activity, but denied needing to vomit. Skin was pale and moist. 10/7/09 ER records received for date 9/21/09. DC DX: seizure vs. syncope. Presenting sx: As pt was receiving vaccine, she arched her back, may have had loss of consciousness and/or seizure. Pt states in ER feeling fine. Assessment: PE WNL. ICD9 codes: 781.0, 780.39.

Other Meds: None

Lab Data: Patient transported by ambulance to PV ER. Testing done on blood (chemistries) and urine (UA and pregnancy test); all within normal limits other than slightly elevated Chloride level. No radiolgic testing done. Diagnosis was seizure vs.

History: Told by guardian/translator that patient had a history of seizures. She had not had any seizures since coming to the US in 2/09. She saw a doctor and had blood work done on 9/21, but was on no meds a time of vaccinations. 10/7/09 ER records received for date 9/21/09. PMH: 3 previous sycopal episodes in past 3-4 yrs.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **358304-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	03-Aug-2009	16-Aug-2009	13	24-Sep-2009	27-Oct-2009	CA		27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294Y	3	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal distension, Discomfort, Flatulence

Symptom Text: Abdominal bloating, gassiness, discomfort for several weeks, beginning one week after each dose of GARDASIL and progressively worse.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **358353-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-Jul-2009	20-Jul-2009	0	25-Sep-2009	28-Sep-2009	FR	WAES0909USA02876	28-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0773X	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Alanine aminotransferase, Alanine aminotransferase normal, Aspartate aminotransferase normal, Blood bilirubin, Blood bilirubin normal, Blood chloride, Blood lactate dehydrogenase, Blood potassium, Blood smear test normal, Blood sodium, C-reactive protein, Epstein-Barr virus antibody negative, Haemoglobin normal, Idiopathic thrombocytopenic purpura, Mouth haemorrhage, Nausea, No reaction on previous exposure to drug, Petechiae, Platelet count decreased, Pyrexia, Red blood cell sedimentation rate, White blood cell count

Symptom Text: Initial case reported on 17-SEP-2009 by Health Authority (HA reference number DK-DKMA-20092675) to local subsidiary. It was reported that a 13 year old female was vaccinated with her third dose of GARDASIL (intramuscularly, batch number NK14370, lot number NJ28270) on 20-JUL-2009. Later on the same day (not further specified), the patient experienced febrile reaction and nausea. It was reported that the patient on the day of vaccination was babysitting a child which vomited. Five days later on 25-JUL-2009 the patient developed petechia on the legs which spread to general petechia. Ten days after vaccination on 30-JUL-2009 the patient was admitted to a hospital ward for children with petechia on the skin and on oral mucosa. At this time, the patient did not have fever (cessation date not reported). Idiopathic thrombocytopenia purpura was suspected. Laboratory analysis showed thrombocyte count of 1 x 10E9/L (low), normal Hgb, Leu., CRP, SR, ASAT, ALAT, LD, s-bilirubin and sodium, potassium and chloride (not further specified). The patient was examined for Epstein-Barr virus, parovirus CM virus with no signs of active disease. A blood smear showed no signs of leukemia. The patient was vaccinated with second dose of GARDASIL (batch number NJ50800, lot number 0773x, route and site of administration not reported) on an unspecified date in 2009. No adverse events were reported. The patient was vaccinated with first dose of GARDASIL (batch number NJ38950, lot number 0747X, route and site of administration not reported) on 19-JAN-2009. No adverse events reported. At the time of the report, the patient was recovering from idiopathic thrombocytopenia purpura (thrombocyte count was normalizing) and was treated on an outpatient basis. The patient did not suffer from any disease at the time of vaccination. Other business partner numbers included: E2009-08754. Additional information has been requested.

Other Meds: Unknown

Lab Data: platelet count, 25Jul09, 1, 10E9/L, Low

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **358354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		25-Sep-2009	28-Sep-2009	--	WAES0909USA03497	28-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Neurological symptom

Symptom Text: Information has been received from the patient's mother concerning her daughter with allergy to latex, who on an unknown date was vaccinated with a dose of GARDASIL. The patient's mother stated that on an unknown date, her daughter experienced symptoms that "mimicked a stroke". Upon internal review "mimicked a stroke" was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Latex allergy

Prex Vax Illns:

Vaers Id: **358367-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		25-Sep-2009	28-Sep-2009	FR	WAES0909USA02882	28-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Glomerulonephritis membranous, Nephrotic syndrome

Symptom Text: Information has been received from a Health care professional (physician nephrologist) concerning a young female patient who on an unspecified date was vaccinated with the first dose of GARDASIL (Lot #, route and site of administration not reported). It was reported that after vaccination (date not reported) the patient developed a nephrotic syndrome due to membranous glomerulonephritis without glomerular filtrate deterioration. The reporting physician considered glomerulonephritis membranous and nephrotic syndrome to be other important medical events by the reporting physician. Other business partner numbers include: E2009-08752. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358376-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Sep-2009	25-Sep-2009	0	25-Sep-2009	05-Oct-2009	IA		06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3011AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B0368A	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0672Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB244AD	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: immediate syncope event following vaccination.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358381-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Sep-2009	14-Sep-2009	0	25-Sep-2009	05-Oct-2009	IA		06-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B036BA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2670AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0672Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB244AD	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: immediate syncope event folling all shots

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358392-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	30-Jun-2009	01-Jul-2009	1	25-Sep-2009	06-Oct-2009	FL		06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	?	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Fatigue, Headache, Joint stiffness, Musculoskeletal stiffness, Neck pain, Pain, Pyrexia, Syncope

Symptom Text: dizzy, very bad headache, stiff joints, stiff and painful neck, trouble breathing and short of breath, fever, ligh-headed, tired, whole body sore to the touch--fainting. felt like I was becoming paralayzed-- was like this for 2 days. I WILL NOT HAVE THE 3RD DOSE.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **358409-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	U	26-Sep-2009	26-Sep-2009	0	26-Sep-2009	06-Oct-2009	--		06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	ASK DR	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Syncope

Symptom Text: About 1 to 2 minutes after she got her shot she got dizzy and fainted, falling off the table at the office

Other Meds: Focalin

Lab Data: none

History: ADHD

Prex Illness: None

Prex Vax Illns: none~ ()~NULL~~In Patient|none~ ()~NULL~~In Sibling1

Vaers Id: **358417-1 (S)** **Related reports:** 358417-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Aug-2009	18-Sep-2009	44	26-Sep-2009	02-Oct-2009	CA		16-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	2	Right arm	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Bacterial infection, Blindness unilateral, Eye inflammation, Iris disorder, Migraine, Ocular hyperaemia, Photophobia, Ulcerative keratitis

Symptom Text: Since receiving the Gardisil vaccination, patient has suffered frequent migraine headaches, bloodshot eyes, and extreme sensitivity to light. Within a week or two of the 3rd & final vaccination, eyes became extremely bloodshot. On 9/18/09, visit to NCAA team doctor for bloodshot eyes resulted in diagnosis of inflamed iris and two spots on the cornea. On 9/19/09, when patient woke up in the morning, was unable to see out of the left eye. Taken to emergency room and was diagnosed with corneal ulcer and bacterial infection. Has been referred to cornea specialists for treatment. Treatment for past 9 days has involved hourly eyedrops and/or ointments applied to the eye, 24 hours a day. Doctor now concerned about thinning of cells and the surface of the eye being broken as a result of the bacteria attacking the cornea. These events have had an adverse number of effects on her life in addition to the medical concerns.10/19/2009 received Opthalmologist records for dates 9/19 and 9/20/2009. Patient with c/o's decreased vision, eye pain. PE revealed discharge lt eye, Rx'd ABX eye gtts. DC

Other Meds: Birth Control

Lab Data: Corneal Ulcer & Unknown Bacterial Infection causing loss of sight in left eye. 8/5/09 PPD administered.

History: None - Patient has been extremely healthy all her life. Eats well and exercises daily PMH: none Allergies: NKDA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **358417-2 (S)** **Related reports:** 358417-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Aug-2009	18-Sep-2009	44	10-Dec-2009	11-Dec-2009	--	WAES0911USA01149	11-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	2	Right arm	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Bacterial infection, Blindness unilateral, Iritis, Migraine, Ocular hyperaemia, Photophobia, Ulcerative keratitis

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. An 18 year old female with no known medical history, she has been extremely healthy all her life and eats well and exercises daily, was vaccinated with a third dose of GARDASIL (lot# 663452/0671Y) in the right arm (route not reported) on 05-AUG-2009. Concomitant therapy included "birth control' (therapy unspecified) and tuberculin purified protein derivative (PPD) was administered on 05-AUG-2009. Since receiving the GARDASIL vaccination, the patient has suffered frequent migraine headaches, bloodshot eyes, and extreme sensitivity to light. Within a week or two of the third and final vaccination, eyes became extremely bloodshot. On 18-SEP-2009, the patient visit to team doctor for bloodshot eyes resulted in diagnosis of inflamed iris and two spots on the cornea. On 19-SEP-2009, when patient woke up in the morning, she was unable to see out of the left eye. She was taken to emergency room and was diagnosed with corneal ulcer and bacterial infection. She has been referred to cornea specialists for treatment. Treatment for past 9 days has involved hourly eyedrops and/or ointments applied to the eye, 24 hours a day. Doctor now concerned about thinning of cells and the surface of the eye being broken as a result of the bacteria attacking the cornea. These events have had an adverse number of effects on her life in addition to the medical concerns. Corneal ulcer and unknown bacterial infection caused loss of sight in left eye. The listing indicated that one or more of the events was considered to be immediately life-threatening. The originally reporting source was not provided. The VAER ID# is 358417. No further information is available. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all re

Other Meds: hormonal contraceptives; tuberculin purified protein

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **358463-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	23-Sep-2009	23-Sep-2009	0	25-Sep-2009	27-Oct-2009	IL		27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0975Y	1	Unknown	Subcutaneously	
	TDAP	SANOFI PASTEUR	UT486DA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0702X	0	Unknown	Intramuscular	
	HEPA	MERCK & CO. INC.	0605Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Pain in extremity

Symptom Text: Pain in upper left arm-unable to lift left arm.

Other Meds: None

Lab Data: None

History: Birth defects-congenital anomalies both arms, hands

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358471-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		15-Sep-2009	20-Oct-2009	WA		20-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Vision blurred

Symptom Text: Complaints of blurry vision, R knee pain, fatigue. Started after 1st HPV vaccine 3-10-09. HPV# 2 5/12/09. HPV#3 9-15-09. Not seen by MD until 9/24/09. VA 20/20 ou, R knee exam normal, hemogram --> no anemia.

Other Meds:

Lab Data: H/H 52.7/39; WBC 6500; pH 228; VA 20/20 ou

History: Congen hip dysplasia

Prex Illness:

Prex Vax Illns:

Vaers Id: **358486-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Dec-2008	27-Feb-2009	68	28-Sep-2009	05-Oct-2009	OH		26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Computerised tomogram abnormal, Condition aggravated, Conversion disorder, Dizziness, Emotional disorder, Fallopian tube disorder, Gait disturbance, Haematochezia, Intentional self-injury, Laparoscopy, Ovarian disorder, Pelvic inflammatory disease, Renal disorder, Road traffic accident, Scan brain, Syncope, Unresponsive to stimuli

Symptom Text: Currently 16 years old, did received three GARDASIL shots, the first one being in February 21st of 2008, second being April 24 th of 2008, and the third one being February 19th of t2009. The patient has had some previous with abdominal pain and a headache for which she was seeing Neurology and Gastroenterology. After her GARDASIL shot on February 21, 2008, the patient had an episode February 27th having emotional due to a boyfriend problems, did take a knife and made some small cuts in her wrists. Seen through the emergency room and thought to be stable, sent home and was being followed by a counselor in April of 2008. It was thought that she might benefit from some antidepressant medication and was started on Zoloft 25mg once a day. The patient was seen later, had her Zoloft increased to 50mg once a day. She did receive a second GARDASIL shot on April 24,2008 . The patient continued on the Zoloft for a few months and it was subsequently self-discontinued. For the most part, the patient did well over the ensuing next 12 months until April 23, 2009, when she was in a car accident, for which she had a CT scan of her abdomen, which did not reveal any abnormalities from the car accident, but did reveal ovarian and fallopian tube abnormalities thought to be consistent with pelvic inflammatory disease and was admitted to Hospital for antibiotics and was also seen by GYN. Also noted to have some mild kidney abnormality of uncertain significance. Nephrology just recommended follow up ultrasound. The patient did well for a while, then started having some more abdominal pain with some blood in her stools. She had previously seen Gastroenterology who had planned on giving her endoscopy and colonoscopy. If she had problems, started back on some Mira lax and Prevacid. A follow up appointment with Gastroenterology was scheduled. In the interim, the patient also had a laparoscopy by GYN in May, now waiting for a return visit to Gastroenterology. The patient started having more abdominal problems and dizziness, was admitted to t

Other Meds:

Lab Data: Dx studies: CT Abd/Pel abnormal, noted free fluid in pelvis, Pelvic US confirmed TOA (Tubo-ovarian abscess) Lap surgery done 5/2009 Lab/dx studies from ED visit 8/28/2009 Lab : CBC, CMP WNL Dx studies/Xrays: Pelvic US, Abdominal US ne

History: PMH: None Allergies: NKDA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358492-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Aug-2009	11-Aug-2009	0	28-Sep-2009	07-Oct-2009	AR	AR0932	07-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adverse reaction, Feeling abnormal, Hyperhidrosis, Loss of consciousness

Symptom Text: Mother states after left clinic child became diaphoretic and stated felt bad, after got home (~15 mins) child passed out - child woke up and felt better. ~45 mins later, mother took her to dentist and she passed out again. Mother then tool her to ER - Dr stated it was an adverse reaction

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358496-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Sep-2009	Unknown		28-Sep-2009	07-Oct-2009	PA		07-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0802Y	1	Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041BA	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Vaccines administered prior to results of pregnancy test. No symptoms at present time.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **358500-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	04-Aug-2009	04-Aug-2009	0	28-Sep-2009	07-Oct-2009	MN		21-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0087Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Injection site reaction, Muscular weakness, Musculoskeletal discomfort, Musculoskeletal pain, Myofascial pain syndrome, Oropharyngeal pain, Pharyngitis

Symptom Text: Patient received GARDASIL vaccine at medical clinic on 8/10/09 has ongoing pain left shoulder x 6 weeks after injection. Arm strength weaker on left. No relief with ibuprofen or TYLENOL. 10/ 19/09 Received medical records from date 9/24/09. DX: injection site reaction, myofacial pain, pharyngitis. SX: pt presented to office with c/o left shoulder pain and weakness since last HPV vaccine 8/10/09. c/o right side neck gland tender, sore throat. Assessment: Normal ROM left arm, decreased strength left arm, tender over left deltoid, (-)redness, (-)swelling, (+)mild enlargement right pharyngeal tonsil.

Other Meds:

Lab Data: CPK with so enzymes-WNL 10/ 19/09 Received medical records from date 9/24/09 Diagnostics/Labs: rapid strep(-), CPK WNL.

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358518-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-May-2007	01-Jul-2007	61	28-Sep-2009	29-Sep-2009	--	WAES0909USA03134	29-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Muscle contractions involuntary, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning his 21 year old daughter with TEGRETOL allergy who in May 2007, was vaccinated with the first dose of GARDASIL (lot number not reported). Two months later, in approximately July 2007, the patient experienced her first seizure. On an unspecified date the patient was vaccinated with the second dose of GARDASIL (lot number not reported). Two months after the second dose the patient experienced another seizure. On an unspecified date the patient was vaccinated with the third dose of GARDASIL (lot number not reported). After the third dose, the patient still experienced seizures. It was reported that "at one point, she was taken to the emergency room because her roommates were worried about her" and "most recently the left side of her body has been locking up and contracting, and last night (20-SEP-2009) it spread to her right side". There were some office visits. Unspecified lab studies performed, and no result provided. At the time of the report, the patient not recovered. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **358523-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Dec-2008	Unknown		28-Sep-2009	29-Sep-2009	FR	WAES0909USA03204	29-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1697U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a Practice Nurse (P.N) via CSL as part of a business agreement for the pregnancy registry for GARDASIL concerning an 18 year old female patient who was reported to be an smoker and alcohol user who on 03-DEC-2008 was vaccinated with a dose of GARDASIL (Lot # 1697U and Batch # NH48330). It was reported that she discovered she was pregnant around the beginning of December last year, in her first trimester of pregnancy. On an unspecified date an elective abortion was carried out. Upon internal review elective abortion was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown) Smoker; Alcohol use

Prex Vax Illns:

Vaers Id: **358543-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	25-Sep-2009	25-Sep-2009	0	28-Sep-2009	07-Oct-2009	MA		07-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB711AA	2	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0229X	2	Right arm	Intramuscular	
	IPV	SANOFI PASTEUR	B000-9	2	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3018AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site pain, Pyrexia

Symptom Text: PT CALLED TO REPORT PAIN AT INJECTION SITE, FEVERS (DID NOT MEASURE TEMP WITH A THERMOMETER) AND DIZZINESS. HAS BEEN RESTING IN BED, TAKING ADVIL PRN, AND PUSHING FLUIDS. DENIES CONCURRENT FLULIKE SYMPTOMS.

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: 358624-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Aug-2009	25-Aug-2009	14	29-Sep-2009	08-Oct-2009	NC		08-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0313Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Back pain, Cough, Fatigue, Flank pain, Headache, Musculoskeletal chest pain, Nausea, Pain in extremity, Respiratory tract congestion

Symptom Text: approxiametly 2 weeks after dose 3 of Gardisil patient complaining od left hip pain. Seen 9/11/09 cough, leg pain headache, rib pain. Seen 9/15/09 epigastric pain, fatigue, back pain. Seen 09/23/09 flank pain, nausea, cough,congestion

Other Meds: Yaz Zyrtec

Lab Data: Normal CBC,CMP, ESR, Urinalysis, urine culture, Amylase/Lipase, Abdominal Pelvic ultrasound

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358630-1 (S)** **Related reports:** 358630-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	28-May-2009	14-Jul-2009	47	29-Sep-2009	05-Oct-2009	NY		16-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294Y	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Chest pain, Dizziness, Dyspnoea, Pulmonary embolism, Urinary tract infection

Symptom Text: Bilateral pulmonary embolism. Coumadin/CT Scan. 10/14/09 Hospital records received for dates 7/14/09 to 7/21/09. DX: Bilateral Pulmonary embolism, UTI. Presenting SX: chest pain x1 week, shortness of breath, lightheadedness, "almost fainting" feeling. Assessment: relatively normal will perform labs/diagnostics. Pt has desk job, and 2 short flights within past week. Gardasil vax 5/08. Pt treated with anticoagulation therapy and dc. ICD9 codes: 599.0, 427.89, 415.19

Other Meds: NUVARING

Lab Data: CT scan 10/14/09 Hospital records received for dates 7/14/09 to 7/21/09 Diagnostics/Labs: D-dimer 844, CT(+)Bilateral pulmonary emboli. EKG-abnormal, cardiac echo WNL, CXR (-), Troponin WNL, UA(+)WBC and (+)Blood, HCT 34(L), platelets WNL,

History: none 10/14/09 Hospital records received for dates 7/14/09 to 7/21/09 PMH: appendectomy, previous smoker.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **358630-2 (S)** **Related reports:** 358630-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	28-May-2009	14-Jul-2009	47	03-Dec-2009	04-Dec-2009	--	WAES0911USA01156	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294Y	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Chest pain, Dizziness, Dyspnoea, Pulmonary embolism, Urinary tract infection

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 23 year old female with a history of appendicectomy and previous smoker was vaccinated with the first dose of GARDASIL in May 2008 and was vaccinated with the second dose of GARDASIL (lot # 0294Y) in left arm on 28-MAY-2009. Concomitant therapy included NUVARING. On 14-JUL-2009 the patient experienced chest pain, dizziness, dyspnoea, pulmonary embolism and urinary tract infection and was hospitalized. Hospital records was received for dates 14-JUL-2009 to 21-JUL-2009. Coumadin/CT scan showed bilateral pulmonary embolism. D-dimer was 844, electrocardiogram (EKG) was abnormal, cardiac echo was within normal limits, chest X-ray (-), troponin was within normal limits, urinalysis test (+) white blood cell count (+) blood, whole blood hematocrit was 34L and platelets was within normal limits. The diagnosis was bilateral pulmonary embolism and urinary tract infection. The symptoms were chest pain for 1 week, shortness of breath, lightheadedness, "almost fainting" feeling. Assessment: relatively normal would perform lab/diagnostics. The patient had desk job and 2 short flights within past week. Patient was treated with anticoagulation therapy and discharged. Chest pain, dizziness, dyspnoea, pulmonary embolism and urinary tract infection were considered to be immediately life-threatening. No further information is available. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released. The original reporting source was not provided. The VAERS ID # is 358630.

Other Meds: NUVARING

Lab Data: computed axial, (+) bilateral pulmonary emboli; electrocardiogram, abnormal; echocardiography, within normal limits; chest X-ray, (-); plasma D-dimer test, 844; serum TnT, within normal limits; urinalysis, (+); WBC count, (+); hematocrit, 3

History: Appendicectomy; Ex-smoker

Prex Illness:

Prex Vax Illns:

Vaers Id: 358667-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Jun-2009	14-Sep-2009	76	29-Sep-2009	30-Sep-2009	NC	WAES0909USA03143	30-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper

Symptom Text: Information has been received from a physician concerning his 16 year old daughter with no pertinent medical history and no known drug allergies who on 30-JUN-2009 was vaccinated IM with a first 0.5ml dose of GARDASIL (lot# not reported). There was no concomitant medication. On 14-SEP-2009 the patient experienced severe, crampy, intermittent left upper abdominal quadrant pain. On 19-SEP-2009 the patient was admitted to hospital. Blood work, computed axial tomography (CT) scan, and abdominal magnetic resonance imaging (MRI) were normal. The test results on the patient came back as positive for Epstein Barr virus. The patient received pain management with hydrocodone and intravenous morphine. The patient was discharged on 20-SEP-2009. At the time of the report, the patient had not recovered. Severe, crampy, intermittent left upper abdominal quadrant pain and positive for epstein barr virus were considered to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: Diagnostic laboratory, 09/19/09, Blood work was normal; Computed axial, 09/19/09, normal; Magnetic resonance, 09/19/09, abdominal: normal; Serum Epstein-Barr, 09/19?/09, positive

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **358668-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Sep-2009	30-Sep-2009	--	WAES0909USA04143	30-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a consumer via Internet. The consumer stated that a perfectly healthy teenager girl received GARDASIL. After she received GARDASIL shot, she "was fighting for her life." Upon internal review fighting for her life was considered to be an other important medical event. Attempts to verify the existence of an identifiable patient have been unsuccessful. This is one of several reports provided by the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358671-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Sep-2009	03-Sep-2009	0	29-Sep-2009	30-Sep-2009	PA	WAES0909USA03701	30-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 13 year old female patient with penicillin and nuts allergy and no other relevant history, who on 03-SEP-2009 was vaccinated IM in her left arm with a first dose GARDASIL (lot # 663452/0671Y). There was no concomitant medication. On 03-SEP-2009 the patient experienced numbness on her upper left arm and tingling on her lower left arm and leg after receiving GARDASIL. No laboratory or diagnostic tests were performed. The patient was seen for an office visit. The patient's final outcome was not reported. The reporting physician considered that numbness and tingling were disabling. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy; Allergy to nuts

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358675-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	10-Jun-2009	10-Jun-2009	0	29-Sep-2009	30-Sep-2009	FL	WAES0909USA03765	30-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2995AA		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2640AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Muscle rigidity, Syncope

Symptom Text: Initial and follow-up information has been received from a registered nurse concerning a 19 year old female patient who on 10-JUN-2009 was vaccinated with the first 0.5 ml dose of GARDASIL (lot# 661531/1311X) intramuscularly in the left arm. Concomitant vaccinations administered on 10-JUN-2009 included a dose of ADACEL (manufacturer Sanofi, lot# C2995AA) in the left arm and a dose of MENACTRA (Sanofi Pasteur, lot# U2640AA) in the right arm. Within three to five minutes the patient had syncope with a loss of consciousness and had rigidity of posture which lasted for about ten minutes, which was also described as a seizure. The patient regained consciousness and recovered without any medical interventions. The patient was ordered a follow-up EEG. The patient's mother declined a follow-up EEG test for her daughter. The patient left the physician's office with her mother. The patient will not receive the second dose of GARDASIL. Upon internal review, possible seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **358691-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Sep-2009	15-Sep-2009	0	29-Sep-2009	27-Oct-2009	CA		27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Face injury, Fall, Head injury, Nasopharyngitis, Presyncope, Tearfulness

Symptom Text: Patient became cold and clammy, tearful, fell off exam table onto floor and hit face and head-vasovagal reaction.

Other Meds:

Lab Data: CT brain-negative, CT neck-negative, CT maxillofacial-negative

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358699-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Aug-2009	03-Aug-2009	0	29-Sep-2009	09-Oct-2009	NH		09-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0000000	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Dizziness, Headache, Injection site pain, Loss of consciousness, Opisthotonus

Symptom Text: My daughter experienced a very painful shot of the gardasil. While we were walking to the check out she felt dizzy, sat in a chair next to me..passed and hit her head against the wall. Her head and body were arched over the side/back of the chair. I thought she was having a seizure but was told her body was like that from just passing out. She woke up woozy and had a sore head and ankle (which apparantly hit or got twisted in some part of the chair.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Sep-2009	17-Sep-2009	1	29-Sep-2009	27-Oct-2009	MO		28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0006404501	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0006482700	1	Right arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	5816082501	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site warmth

Symptom Text: 3 x 3 inch erythema, warmth and pain R arm.

Other Meds:

Lab Data: None

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: 358739-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Aug-2009	27-Aug-2009	10	29-Sep-2009	30-Sep-2009	FR	WAES0909USA03678	30-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Deep vein thrombosis, Pain in extremity

Symptom Text: Information has been received from a Health Authority (HA reference number 2009-03713) concerning a 15-year-old female with who on 17-AUG-2009 was vaccinated intramuscularly with her first dose of GARDASIL (lot number and batch number not reported). On 27-AUG-2009, ten days after vaccination, the patient developed searing pain in her left calf. This was the first time she had experience such an episode. A slight improvement followed before a worsening of symptoms, starting on 29-AUG-2009. A venous Duplex sonography was performed on 01-SEP-2009. Deep vein thrombosis of the lower leg was diagnosed. The patient was being treated with SINTROM. The therapy was planned for three months. The patient was not hospitalized. There was no known risk factors (obesity, oral contraceptives, smoking or pregnancy). An evaluation for possible hypercoagulability conditions was planned after the course of anticoagulant therapy The reporting physician planned to give the second dose of GARDASIL while the patient was still taking SINTROM. At the time of the report, she had not fully recovered. It was noted that the Health Authority assessed the causal relationship between thrombosis venous deep and GARDASIL as possible. Other business partner numbers included: E2009-08871. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 01Sep09, Venous Duplex sonography: Deep vein thrombosis of the lower leg was diagnosed

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **358741-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		29-Sep-2009	30-Sep-2009	--	WAES0909USA03484	30-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired

Symptom Text: Information has been received from a consumer via internet blog concerning her 13 year old daughter who was vaccinated with a dose of GARDASIL. According with the patient's mother, the patient was completely disabled for the past year in 2008. The reporter indicated that because of GARDASIL, her daughter was "one less student", "one less active child", "one less in every aspect o her life". The reporter also stated that she spent the last year sitting by her child's bedside wondering if she would "die in her sleep". The reporter also indicated that "this vaccine has cost my daughter a year of her life and tens of thousands in medical bills". The patient sought medical attention through a physician. The patient's outcome is unknown. Attempts to verify the existence of an identifiable patient have been unsuccessful. No further information is available. The patient was being treated in two hospitals.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358742-1** **Related reports:** 358742-2; 358742-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Sep-2009	15-Sep-2009	0	29-Sep-2009	16-Oct-2009	VA		12-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Limb discomfort, Myalgia

Symptom Text: Myalgia - severe. Chest pain tightness in lower arms.

Other Meds:

Lab Data: ESR; CBC; CRP; CMP; ANA.

History: Allergic rhinitis.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358742-2** **Related reports:** 358742-1; 358742-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Sep-2009	15-Sep-2009	0	09-Oct-2009	22-Oct-2009	VA		07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Back pain, Chest pain, Dizziness, Hot flush, Metal poisoning, Migraine, Myalgia, Neck pain, Sleep disorder

Symptom Text: Chest pain, myalgia-severe,back pain, neck pain, muscle pain, stomach aches, chronic migraine headaches, dizziness, hot flashes, sleep issues, elevated SED, Al toxicity

Other Meds:

Lab Data: ESR, CBC, CRP, CMP, ANA SED Rate Elevated Live Blood test displaying weakened immune system and chylous

History:

Prex Illness: Chest pain,muscle pain, shooting pains

Prex Vax Illns: chest pain, muscle pain~HPV (Gardasil)~1~11.33~Patient

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Vaers Id: **358742-3** **Related reports:** 358742-1; 358742-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Sep-2009	15-Sep-2009	0	09-Oct-2009	29-Oct-2009	VA		30-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Back disorder, Chest pain, Dysuria, Fatigue, Headache, Muscle tightness, Muscular weakness, Myalgia, Oedema peripheral, Pain in extremity, Reflex test normal, Rhinorrhoea, Vulvovaginal pain

Symptom Text: Myalgia-severe, chest pain tightness in lower arms. 10/05/09 Vaccine records received. Medical record received for DOS 7/14/09 - 9/15/09. Chest pain status post 1st Gardasil vaccine. MD offered office visit but mom delclined. 2nd vaccine and c/o arm and muscle pain all over. Tired muscles. Muscle weakness. Vaginal pain. Lower arm edema. Dysuria. Frontal HA. Nasal d/c alternating from clear to thick. Insomnia s/t pain. C/O swollen back.Abdominal pain. Ibuprofen helped. Reflexes and strength equal bil. Normal sensation.

Other Meds:

Lab Data: ESR, CBC, CRP, CMP, ANA

History: Allergic Rhinitis. ALlergies: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **358744-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Jan-2009	Unknown		29-Sep-2009	30-Sep-2009	--	WAES0909USA03482	30-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Alopecia, Asthenia, Back pain, Chest pain, Computerised tomogram normal, Diarrhoea, Dizziness, Dyskinesia, Dyspnoea, Feeling abnormal, Gastric disorder, Headache, Heart rate increased, Hypoaesthesia, Malaise, Nausea, Neck pain, Pain, Paraesthesia, Visual impairment, Weight decreased

Symptom Text: Information has been received from the patient's mother via internet. The mother stated that her 16 year old daughter was injured by GARDASIL. On 09-JAN-2009, the patient was vaccinated with the first dose of GARDASIL and on 09-MAR-2008 with the second dose of GARDASIL. Before GARDASIL, she was happy, healthy and vibrant teenager. Since GARDASIL, the patient was sick every day of her life. She had dizziness, overall weakness, numbness and tingling in both legs and left arm, back pain, neck pain, pressure headaches, vision problems, breathing problems, chest pains, racing heartbeats, brain fog, stomach problems, nausea, diarrhea, weight loss, hair loss, jerking all over spells, the list goes on. She was and a/B student but failed her 10th grade year because she was too sick to retain what she was trying to learn (brain fog). she was no longer had energy to go off with her friends. Most days she lays in bed, in pain. The patient had been in the emergency room twice, once by ambulance for stopping breathing 3 times. She was seen several doctors. She had CT scan done. All tests come back normal (which is typical with all of the injured GARDASIL vaccine girls). Her blood panel showed high on immunoglobulin E (131H) and Anti streptolysin O (208H) which the doctor "thought" was rheumatic fever. Another doctor had said he did not believe she had rheumatic fever. Brain fog and energy increased were considered to be disability. This is one of several reports provided by the same source. No further information is available.

Other Meds: Unknown

Lab Data: hematology, ?/?/09, blood panel: high on immunoglobulin E (131H) and Anti streptolysin O (208H)

History:

Prex Illness: Gastric disorder

Prex Vax Illns:

Vaers Id: **358746-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Sep-2009	29-Sep-2009	0	29-Sep-2009	08-Oct-2009	LA		08-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Posture abnormal

Symptom Text: Approximately 3 minutes after Gardasil injection, patient began slumping forward in her chair, and then began slight jerking movements. Patient exhibited these movements for only 5-10 seconds. After sitting for about 15 minutes, patient began feeling better. Patient denies losing consciousness; however, reports "feeling dizzy". Patient has not eaten anything today, but has had a soda. (it is 1:42 p.m. now) DepoProvera was administered immediately after Gardasil in the opposite arm.

Other Meds: DepoProvera

Lab Data: none

History: denies

Prex Illness: denies

Prex Vax Illns:

Vaers Id: 358749-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	04-Aug-2009	04-Aug-2009	0	29-Sep-2009	30-Sep-2009	FR	WAES0909USA00039	30-Sep-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chills, Diarrhoea, Drug eruption, Hypersensitivity, Injection site erythema, Injection site inflammation, Injection site pain, Injection site swelling, Injection site warmth, Malaise, No reaction on previous exposure to drug, Pyrexia, Vomiting

Symptom Text: Information has been received from a physician via CSL as part of a business agreement (manufacturer control # 20090901JV1) concerning a 21 year old female who on 04-AUG-2009 was vaccinated with the third dose of GARDASIL. The patient experienced "massive local swelling at the injection site, intense fever and vomiting on the afternoon of receiving the third dose of GARDASIL (from 04-AUG-2009 to 10-AUG-2009). She saw the physician the next day and was admitted to the hospital the following day (06-AUG-2009). She "had a drip put in" and was discharged on 10-AUG-2009 after blood cultures were taken. Hospital notes stated "severe allergic reaction". Follow up information was received from the physician via discharge referral which reported that the patient with bipolar who on 04-AUG-2009 at 11:30 AM was intramuscularly vaccinated with the third dose of GARDASIL (lot# 663751/1574X, which was the lot # of PNEUMOVAX in her left deltoid. Within 2 hours of injection, the patient had a reaction at around the injection site, erythematous, raised skin, clear margin, warm to touch, 6 cm diameter and radial nerve intact. There was no prior reaction to other GARDASIL injection. No other vaccination given at the same time. The patient had been vomiting and injection site was red inflamed and painful. GP saw the patient on 06-AUG-2009 and gave her oral cephalexin. The patient took paracetamol at 12:00 PM on 06-AUG-2009. The patient presented to ED as increasingly unwell that afternoon. The patient presented with fever, rigors, vomiting, diarrhea and drug rash on her left shoulder. Her temperature was 37 C at triage. The patient was admitted on 06-AUG-2009. The patient recovered entirely with time and I.V. antibiotics and was discharged on 10-AUG-2009. The medications on discharge was dicloxacillin, quetiapine fumarate and sodium valproate. The physician felt that there was a reasonable possibility that the AE's were caused by the GARDASIL vaccine. The correct clock start date for the information containing the validated lot # i

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Bipolar disorder

Prex Vax Illns:

Vaers Id: **358751-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Sep-2007	Unknown		29-Sep-2009	30-Sep-2009	--	WAES0909USA03485	04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Amnesia, Arthralgia, Back pain, Chest pain, Condition aggravated, Confusional state, Convulsion, Fatigue, Irritability, Malaise, Migraine, Nervous system disorder, Staphylococcal infection, Transient ischaemic attack, Weight increased

Symptom Text: Information has been received from a consumer via and internet blog concerning her daughter a student with a history of occasional migraine and pharyngitis streptococcal when younger who in September 2007, was vaccinated with the first dose of GARDASIL (Lot number not reported) and received her second dose of GARDASIL (Lot number not reported) in November 2007. Subsequently on an unspecified date the mother reported that GARDASIL made her daughter sick. It had attacked her daughter's central nervous system. The student now spent most of days confused, irritable, trying to find her past as she can not remember a lot of it. She was an honor student and just graduated in May and could not remember her graduation. She suffered with re-occuring Methicillin-resistant staphylococcal aureus infection (MRSA), chronic fatigue, migraines, hair loss, chest and back pain, weight gain, joint pain, seizures and mini strokes. The reporter stated that her daughter is trying to get her life back and she wont received the third dose of GARDASIL as she realized this was indeed what made her sick. It was unknown if the patient sought medical attention. At the time of the report, the patient's outcome was unknown. Seizures were considered to be an other important medical event. The reporter felt that her daughter symptoms were related to therapy with GARDASIL. Attempts to verify the existence of an identifiable patient and reporter have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Migraine; Pharyngitis streptococcal

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358772-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		29-Sep-2009	27-Oct-2009	OR		28-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crohns disease

Symptom Text: Shortly after receiving the HPV vaccine Patient was diagnosed with Crohns Disease. We have no history in out family.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **358809-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	24-Sep-2009	24-Sep-2009	0	29-Sep-2009	27-Oct-2009	KY		27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site rash, Injection site urticaria, Rash macular, Urticaria

Symptom Text: Maruck/Urticarial rash at injection site and same onto chest

Other Meds: None

Lab Data: Not required

History: asthma, dx 9/11/09 without SOB & CP

Prex Illness: None present

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358823-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Sep-2009	28-Sep-2009	0	29-Sep-2009	27-Oct-2009	NY		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Numbness of mid arm area-more than 24hrs.

Other Meds:

Lab Data: reassurance

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358845-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	29-Sep-2009	29-Sep-2009	0	29-Sep-2009	27-Oct-2009	NY		02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Pt felt asleep for 2 sec, shake Pt arousal A+O x 3. Orange juice given, put student on examination bed, presently smiling and talking with friend. Pt reported every time she takes immunization or given blood she past out and it normal. Instructed student to see MD.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358848-1** **Related reports:** 358848-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	22-Sep-2009	23-Sep-2009	1	29-Sep-2009	27-Oct-2009	ND		27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Body temperature increased, Cough, Flushing, Headache, Increased upper airway secretion, Injection site pain, Local swelling

Symptom Text: Pt reports headache, T-100, Pain @ ankles & knees, swelling at (R) side of neck, vague weakness, symptoms starting 9-23-09 AM. Also pain at injection site. After injection, nurse commented on "flushing"-pt states she was like that before." 9/25/09 Spoke-client who saw Dr yesterday. Client states Dr said she had infection that started prior to vaccine that she was unaware of. Started on antibiotics & feels slightly better today. Coughing up yellow phlegm.

Other Meds: No

Lab Data: None

History: None

Prex Illness: None noted

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358848-2** **Related reports:** 358848-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	22-Sep-2009	23-Sep-2009	1	07-Oct-2009	29-Oct-2009	ND	ND0909	02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Body temperature normal, Cough, Flushing, Headache, Increased upper airway secretion, Infection, Injection site pain, Local swelling

Symptom Text: Patient reports headache, T- 100 degrees, pain at ankles and knees, swelling at Right side of neck, vague weakness, symptoms, starting at 009/23/2009 AM. Also pain at injection site. After injection nurse commented on flushing- patient states she was like that before. 09/25/2009 spoke with client who saw Dr. yesterday. Client states Dr. said she had infection that started prior to vaccine that she was unaware of. Started on antibiotics and feels slightly better today. She is also coughing up yellow phlegm.

Other Meds:

Lab Data: None

History: None

Prex Illness: None noted

Prex Vax Illns:

Vaers Id: **358853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Aug-2009	Unknown		29-Sep-2009	27-Oct-2009	MN		28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event

Symptom Text: Patient received GARDSIL 8/24/09 and returned to clinic 9/8/09 and had positive urine pregnancy test. No testing done 8/24/09. LMP 7/24/09. No physical adverse reaction/symptoms.

Other Meds:

Lab Data: Urine pregnancy/HCG positive 9/8/09

History: None

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **358916-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Apr-2008	03-Jun-2009	422	30-Sep-2009	05-Oct-2009	NY		30-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB256BA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	19878U	1	Left arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Pollakiuria, Type 1 diabetes mellitus

Symptom Text: Diagnosed with Type 1 diabetes two months later. Frequent urination started 6 wks after vaccination and diagnosed with diabetes 8 wks after vaccination. 1/7/2010 PCP records for 2 wellness visits, 4/2008 and 5/2009, on second visit it states patient on an Insulin pump x 2 months, stable HgbA1C, Dx IDDM

Other Meds: nothing

Lab Data: blood tests

History: allergic to sulfa medications PMH: Diabetes , scoliosis Allergies: Sulfa

Prex Illness: none - vaccination was given at regular 11 yr old well child care check up

Prex Vax Illns:

Vaers Id: **358929-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Jun-2009	01-Jun-2009	0	30-Sep-2009	01-Oct-2009	FR	WAES0909POL00003	01-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	TBE

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Monoclonal immunoglobulin present

Symptom Text: Information has been received from a physician concerning a 22 year old female who in April 2009, was vaccinated with the first dose of GARDASIL. In June 2009 the patient was vaccinated with the second dose of GARDASIL. Concomitant therapy included tick-borne encephalitis virus vaccine (FSME IMMUN) (first dose in March 2009 and the second dose in May 2009). In June 2009, the patient experienced monoclonal protein in blood serum. The patient was hospitalized probably in June 2009 (reason not reported) and laboratory tests performed during hospitalization revealed presence of monoclonal protein in blood serum. The patient's monoclonal protein in blood serum persisted. The patient was discharged from hospital and stayed at home. The physician was not sure if monoclonal protein in blood serum was related to therapy with GARDASIL. The tick-borne encephalitis virus vaccine (FSME IMMUN) was considered to be the secondary suspect therapy. The monoclonal protein in blood serum was considered to be an other important medical event by the physician. Additional information is not expected.

Other Meds: Unknown

Lab Data: serum monoclonal proteins test, ??Jun09, present

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358930-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Mar-2009	27-Mar-2009	0	30-Sep-2009	01-Oct-2009	MD	WAES0909USA03531	01-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received from Merck Pregnancy Registry for GARDASIL from a physician concerning a 15 year old female patient who on 27-MAR-2009 was vaccinated with a first dose of GARDASIL (lot # 659655/0940X). On 27-MAY-2009 she received second dose of GARDASIL (lot # 662229/1497X). On an unspecified date the patient became pregnant. Follow up information has been received from a physician concerning the 15 year old female patient with a vaccination history that included five doses of DTaP (manufacturer unknown) on 07-FEB-1994, 07-SEP-1994, 21-JUN-1994, 30-JUN-1995, 25-AUG-1998. A dose of DTaP (Lot number C2556AA) at 12 year old 18-JUL-2006. Three doses of HIB (OMPC) (manufacturer unknown) on 07-FEB-1994, 21-JUN-1994, 30-JUN-1995. Three doses of ENGERIX-B on 18-JUL-2006 (Lot number B256AA), 29-DEC-2006 (Lot number B258AA) and on 01-MAY-2007 (Lot number B319AA). Four doses of POLIO (unspecified) (manufacturer unknown) on 07-FEB-1994, 07-APR-1994, 30-JUN-1995 and on 25-AUG-1998. Two doses of MMR (manufacturer unknown) on 30-JUN-1995 and on 25-AUG-1998. A dose of VARIVAX (Merck) (manufacturer unknown) on 25-AUG-1998. On 27-MAR-2009 the patient was vaccinated with the first dose of GARDASIL and on 27-MAY-2009 received the second dose of GARDASIL. The physician reported that the patient delivered a baby boy by c-section on 07-SEP-2009. On 07-SEP-2009 the patient was born with genetic hypospadias at 34 weeks and weight at birth of 2280 grams. The physician added that discussion with the baby's parents have been made and this condition may be corrected when the baby is 1 year of age. The physician reported that both the mother and the baby are doing well. Upon internal review genetic hypospadias was considered as genetic anomaly and delivered a baby boy by c-section to be as other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 358931-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Sep-2009	22-Sep-2009	1	30-Sep-2009	01-Oct-2009	PA	WAES0909USA03704	09-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Confusional state, Convulsion, Cyanosis, Dyskinesia, Fall, No reaction on previous exposure to drug, Tongue biting, Tongue oedema, Tremor

Symptom Text: Information has been received from a physician and the physician's secretary concerning a 14 year old female patient with no known drug allergies, pertinent medical history or concurrent conditions who on 21-JUL-2009 was vaccinated with the first dose of GARDASIL (Lot # 658271/0558X). The patient did not have any reaction after the first vaccination. On 21-SEP-2009 the patient was vaccinated with the second dose of GARDASIL (lot # 658271/0558X). There was no concomitant therapy and no other vaccines were given on those days. 24 hours after the second vaccination (22-SEP-2009) the patient had a seizure. The patient's mother contact an " Emergency Medical Tech" who informed her it was from the GARDASIL but the patient was not taken to the hospital. The patient was last seen in the office 23-SEP-2009. At the time of the report, the patient's seizure was recovering. The physician had ordered an EEG and recommended the patient to be seen by a pediatric neurologist (name not recorded). Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested. 10/6/09 PCP medical records, consultations, service date 9/23/09. Assessment: First time seizure. Patient presents with hx of right arm jerking, fell to floor, body shaking, turned grey/blue, biting tongue, vomiting. Tongue edematous. Followed by another shaking episode. Does not remember episodes. Patient remains confused.

Other Meds: None

Lab Data: Unknown. 10/6/09 PCP medical records, consultations, service date 9/23/09. LABS and DIAGNOSTICS: EEG - Abnormal. CBC - Platelets 482 thou/cmm (H) Monocytes 9% (H). CHEM - AST 90 U/L (H) ALT 118 U/L (H) BUN mg/dl (L). MRI Brain - Normal.

History: None. 10/6/09 PCP medical records, consultations, service date 9/23/09. When going to sleep bilateral jerks of legs. At times jerking of right arm.

Prex Illness:

Prex Vax Illns:

Vaers Id: 358932-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-May-2009	24-Aug-2009	97	30-Sep-2009	01-Oct-2009	FR	WAES0909USA03927	01-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1285U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dissociative disorder, Quadriparesis

Symptom Text: Information has been received from a health authority under HA reference no. PEI2009020113 concerning a 14 year old female who on 19-MAY-2009 was vaccinated with the first dose of GARDASIL. On 04-AUG-2009 the patient received the second dose of GARDASIL (IM, lot # 1285U, batch # NH24920) into the upper arm. On 24 -AUG-2009 the patient developed a dissociative disorder tetraparesis. The patient was hospitalized for an unspecified time. Several investigations were carried out (including lumbar puncture, EEG, nerve conduction studies, cranial and spinal MRI, blood analysis, neurological and psychological examination) and showed no pathological findings. Psychological examination supported the diagnosis. Organic causes as GUILLAIN-BARRE syndrome, diseases of central and peripheral nerve system that cause paresis and muscle disease were ruled out. At the time of reporting (03-SEP-2009) symptoms had notably improved. File closed. Other business partner numbers include E2009-08894.

Other Meds: Unknown

Lab Data: spinal tap, ??Aug?09, no pathological findings; electroencephalography, ??Aug?09, no pathological findings; nerve conduction study, ??Aug?09, no pathological findings; magnetic resonance imaging, ??Aug?09, no pathological findings; diagnost

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358953-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-Sep-2009	29-Sep-2009	0	30-Sep-2009	16-Oct-2009	KY		16-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Right arm	Unknown	
	FLU	SANOFI PASTEUR	U3185AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Pt fainted 20 min after injection of GARDASIL, FLUZONE and LA BICILLIN injections. Hit head. No LOC. No sequelae noted - Did well after TX.

Other Meds:

Lab Data: None

History:

Prex Illness: Strep

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358968-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Aug-2009	15-Aug-2009	12	29-Sep-2009	27-Oct-2009	--		28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphthous stomatitis, Decreased appetite, Fatigue, Gingival bleeding, Pyrexia

Symptom Text: My daughter received 1 dose of the GARDASIL vaccine and within 10 days had a fever, bleeding gums, canker sores inside the mouth, fatigue, no appetite. No one else in the family or friends were ill.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **358975-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Sep-2009	28-Sep-2009	0	30-Sep-2009	12-Oct-2009	CO		12-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: A few minutes after the immunization of Gardasil, child became extremely dizzy and faint, with no loss of consciousness. Assisted to floor and given fluids. Able to walk out of office 15 minutes after onset.

Other Meds: Loratadaine

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: None~ ()~NULL~~In Patient|None~ ()~NULL~~In Sibling1|None~ ()~NULL~~In Sibling2

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **358980-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	30-Sep-2009	30-Sep-2009	0	30-Sep-2009	12-Oct-2009	TX		13-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0980Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Conversion disorder, Convulsion, Malaise

Symptom Text: Patient received Gardasil vaccine dose #1 on 3/2/2009, Gardasil #2 on 6/9/2009, and Gardasil #3 on 9/30/2009. She reports having a seizure in May, was seen by a neurologist and had a negative workup, and was told she has pseudoseizures and was prescribed Xanax 0.25 mg. She reports her last seizure was 9/2/2009. Approximately 5 minutes after receiving her third Gardasil dose today at 2:15 PM, she complained of "not feeling well" and then began to have a seizure that lasted approximately 5 minutes in duration. She took 0.25 mg of Xanax at the onset of the seizure. She did not suffer any injuries during the seizure and was awake, alert, and responsive during the event. She was ambulatory upon leaving the office and had no complaints. She did admit to not having eaten either breakfast or lunch today.

Other Meds: Prozac, Xanax

Lab Data: none

History: Patient did not state that she has pseudoseizures until after the Gardasil vaccine was administered. She reports a previous diagnosis of ADHD.

Prex Illness: pseudoseizures

Prex Vax Illns:

Vaers Id: **358983-1 (S)** **Related reports:** 358983-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	02-Jun-2009	12-Jun-2009	10	30-Sep-2009	05-Oct-2009	MN		02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968UOB	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Chest discomfort, Computerised tomogram, Cough, Deep vein thrombosis, Dyspnoea, Echocardiogram, Intensive care, Pain in extremity, Pulmonary embolism, Thrombolysis

Symptom Text: Recieved Gardasil HPV Vaccine on 06/02/09, had symptoms of leg pain on 06/07/09 and was hospitalized 06/12/09 with extensive DVT and bilteral PE extensive clot. IVC in the setting of post-partum and heterozygous Factor V leiden. Required thrombolysis with TPA, IVC filter placement and echocardiogram and CT scans. Required Intensive Care Unit stay and anti-coagulation with coumadin for 6 months. 10/16/2009 received hospital records for dates 6/12-6/15/2009. Patient presents 10 days post vaccine with sx of dyspnea , cough, chest tightness and rt leg pain. Tx: IV Heparin, Lovenox SQ, IVC filter placement.

Other Meds: On Subcutaneous heparin secondary to post-partum.

Lab Data: Labs: CBC, CMP WNL, Troponin high at 0.44, PT and PTT elevated, O2 sats low (70's) Dx studies/X-rays: Doppler US rt leg + for DVT, CT Angiogram + for bilateral PE's, EKG norm

History: Previously diagnosed factor v leiden, post-partum 7 weeks on onset of adverse event. PMH: Factor V Leiden Heterozygous Disease, Hx of DVT's 18 mos prior Allergies: NKDA

Prex Illness: Post-partum 6 weeks, factor v leiden on heparin for 6 weeks, prior to pregnancy no medications for anti-coagulation.

Prex Vax Illns:

Vaers Id: **358983-2 (S)** **Related reports:** 358983-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	02-Jun-2009	12-Jun-2009	10	02-Dec-2009	03-Dec-2009	--	WAES0911USA01167	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Chest discomfort, Cough, Deep vein thrombosis, Dyspnoea, Intensive care, Pain in extremity, Pulmonary embolism, Thrombolysis

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 25 year old female with no known drug allergy and a history of factor v Leiden heterozygote disease, deep vein thrombosis 18 months prior, pregnancy (no medications for anti-coagulation prior to pregnancy) and postpartum who on 02-JUN-2009 was vaccinated intramuscularly in left arm with the second dose of GARDASIL (LOT# 660389/1968U). Concomitant therapy included subcutaneous heparin secondary to post-partum. On 07-JUN-2009 the patient had symptoms of leg pain. On 12-JUN-2009, 10 days post vaccination, the patient was hospitalized with extensive deep vein thrombosis and bilateral pulmonary embolism. The patient required thrombolysis with total parenteral alimentation (TPA), intraventricular catheter (IVC) filter placement, echocardiogram and computerized tomogram (CT scans) with the positive result for bilateral pulmonary embolism. Laboratory tests and diagnosis studies were done. Doppler ultrasound in right leg had a positive result for deep vein thrombosis; complete blood cell count (CBC) and "CMP" were within normal limit; troponin was high at 0.44; prothrombin time (PT) and activated partial thromboplastin time (APTT) were elevated; oxygen saturation test was low with 70's; and electrocardiogram (EKG) was normal. The patient stayed in intensive care unit and was prescribed anti-coagulation with COUMADIN for 6 months. On 16-OCT-2009 hospital records for dates of 12-JUN-2009 to 15-JUN-2009 were received. It was reported that the patient also presented with signs of dyspnoea, cough, chest tightness and right leg pain after 10 days of vaccination. The patient treated with IV heparin, subcutaneous LOVENOX and IVC filter placement. Chest discomfort, computerized tomogram, cough, deep vein thrombosis, dyspnoea, echocardiogram, intensive care, pain in extremity, pulmonary embolism and thrombolysis were considered to be immediately life-threatening. The patient required an emergency ro

Other Meds: Heparin

Lab Data: ultrasound, 06/12/09, Doppler US right leg + for DVT; computed axial, 06/12/09, CT Angiogram + for bilateral PE's; electrocardiogram, 06/12/09, normal; diagnostic laboratory, 06/12/09, CMP: WNL; complete blood cell, 06/12/09, WNL; serum tro

History: Deep vein thrombosis; Pregnancy; Postpartum disorder; Factor V Leiden heterozygote

Prex Illness:

Prex Vax Illns:

Vaers Id: **358985-1 (S)** **Related reports:** 358985-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Jun-2009	04-Sep-2009	84	30-Sep-2009	05-Oct-2009	KS		04-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	094OX	1	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB330CA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0492Y	0	Right arm	Subcutaneously	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Anticoagulant therapy, Back pain, Bed rest, Deep vein thrombosis, Femoral artery embolism, Intensive care, Oedema peripheral, Pain in extremity, Pulmonary embolism

Symptom Text: Client developed emboli in lungs and in a large part of the femoral artery. Was hospitalized and in ICU for a number of days. Is currently at home on strict bedrest and being monitored with coumadin therapy. 10/28/09 DC summary and hospital records received for dates 9/9/09 to 9/17/09. DC DX: DVT LLE and bilat. PE. Presenting SX: pt. initially c/o back pain and leg pain x2wks seen by chiropractor, pt. seen in ER with dx DVT and PE. Pt. admitted and given anticoag. therapy. Upon DC, pt stable but on bedrest.

Other Meds: none

Lab Data: Client not treated at this facility. Client was hospitalized at medical center. Dx occurred by CT scan showing large femoral artery thrombosis on 09/08/09. 10/28/09 DC summary and hospital records received for dates 9/9/09 to 9/17/09. Di

History: none 10/28/09 DC summary and hospital records received for dates 9/9/09 to 9/17/09. PMH: depression, anemia, morbid obesity, oral BCP for dysmenorrhea.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **358985-2 (S)** **Related reports:** 358985-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Jun-2009	04-Sep-2009	84	03-Dec-2009	04-Dec-2009	--	WAES0911USA01168	07-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB330CA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0492Y	0	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0940X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Bed rest, Femoral artery embolism, Intensive care, Pulmonary embolism

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 15 year old female with no previous illness or medical history who on 12-JUN-2009 was vaccinated with a second dose of GARDASIL intramuscularly into the left arm (lot # 659655/0940X), a first dose of HAVRIX intramuscularly into the right arm (lot # AHAVB330CA) and a first dose of VARIVAX (Merck) subcutaneously into the right arm (lot # 663759/0492Y). 84 days post the vaccination, on 04-SEP-2009 the patient experienced bed rest, femoral artery embolism, intensive care and pulmonary embolism and was hospitalized. It was reported that the patient developed emboli in lungs and in a large part of the femoral artery. The patient was hospitalized at a medical center and in intensive care unit for a number of days. It was reported that the patient was not treated at this facility. Diagnosis occurred by CT scan showing large femoral artery thrombosis on 08-SEP-2009. The patient was currently at home on strict bed rest and being monitored with COUMADIN therapy. The listing indicated that one or more of the events required hospitalization, extended hospital stay and was considered to be immediately life-threatening. No further information is available. The original reporter was not provided. The VAERS ID # is 358985. A standard lot check investigation for VARIVAX (Merck) (lot # 663759/0492Y) was finalized. All in-process quality checks for the lot number (lot # 663759/0492Y) in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot (VARIVAX (Merck), lot # 663759/0492Y) met the requirements of the Agency and was released.

Other Meds: Unknown

Lab Data: computed axial, 09/08/09, large femoral artery thrombosis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **358992-1** **Related reports:** 358992-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	13-Apr-2007	Unknown		30-Sep-2009	02-Oct-2009	MN		01-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal distension, Abdominal pain, Acne, Activities of daily living impaired, Adverse reaction, Anaphylactic reaction, Chest discomfort, Condition aggravated, Diarrhoea, Dizziness, Dysgeusia, Dyspnoea, Fatigue, Feeling abnormal, Flushing, Food intolerance, Gastrooesophageal reflux disease, Glossodynia, Injection site pain, Lymphadenopathy, Memory impairment, Menstruation irregular, Muscular weakness, Oedema peripheral, Oral pruritus, Pain in extremity, Palpitations, Rash, Rash erythematous, Respiratory distress, Sensation of heaviness, Sinusitis, Skin disorder, Stridor, Swollen tongue, Throat tightness, Thrombocytopenia, Tonsillar hypertrophy, Tooth discolouration, Type I hypersensitivity, Urticaria, Vaccine positive rechallenge, Vocal cord disorder, Wheezing

Symptom Text: Notable increase in allergic reactivity and unwellness after first shot. Shot extremely painful going in. Patient has high pain tolerance, and stated it was the most painful thing that ever happened to her. Left tonsil and lymph node in left arm swollen and painful. After second shot anaphylactic reactions with symptoms increasing and cascading into respiratory distress, feeling heavy pressure on chest, severe digestive issues. Muscle heaviness and dibilitating fatigue and mental fog. Heaviness and weakness more pronounced in limbs. Symptoms exacerbated by even minor exertion. Each episode lasted longer than previous and became disabling to the point patient needed wheelchair. Could not stand up to shower, or raise arms to wash hair. Became airborne and skin reactive to strong chemical and food odors. Heart palpitations. Dizziness and faint feelings. Intolerant of even trace amounts of citric acid, and soy lecithin. Intolerant of all fruits, all vegetables or products source from them. Did not have menstruation for almost 2 years. Now has heavy cycles lasting weeks. Metallic taste in mouth. Heavy grey buildup on teeth despite no change in oral hygiene (meticulous oral hygiene). Severe skin problems on face. All over bloating, especially in face and abdomen. Rashes, hives, tongue swelling, painful eruptions on tongue. Episode of tongue swelling witnessed by allergist upon accidental exposure in office to trigger. Seen by Allergists, ENTs, Gastroenterlogists, Speech Therapist, Dietician, Screened for Asthma (negative), Multiple blood tests, and CT scans. Given protocol of multiple antihistamines, Gastrocrom, nebulizer. No effect. Seen at Neurology, various MRIs. Seen by Allergist, and Neurologists. Seen by PA. Had to take medical leave from college. Acupuncture for past year. 10/22/09 and 10/23/09 Medical records received from dates 9/11/08 to 5/6/09 DX: Anaphylactic reaction, secondary to multiple food products, worse with citric acid.Presenting symptoms: Pt. with strong complex history of allergic

Other Meds: Zyrtec D, Depoprovera

Lab Data: MRIs, CT scans, Blood tests for allergic disease indicators. All normal. Ischemic forearm test 10/22/09 and 10/23/09 Medical records received from dates 9/11/08 to 5/6/09 Diagnostics/Labs: CT sinus(-), PFT WNL, Ischemic Exercise test for

History: Allergic to Dairy, egg, peanut, penicillin, ragweed, dust. 10/22/09 and 10/23/09 Medical records received from dates 9/11/08 to 5/6/09 PMH: anaphylactic reactions, multiple food allergies including peanuts, dairy, eggs, citric acid. PCN allergy, cefuroxime allergy. Pneumonia, migraines, syncope, menorrhagia, vocal cord dysfunction.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **358992-2** **Related reports:** 358992-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	13-Apr-2007	Unknown		02-Oct-2009	29-Oct-2009	MN		11-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT General physical health deterioration, Hypersensitivity, Neurological symptom

Symptom Text: Pt vaccinated in clinic. No immediate symptoms, signs of AE. Pts mother called clinic 9/23/09 to request records of injections, lot number & GARDASIL injections and lot numbers due to daughter having "serious health problems, that doctors think may be related to the vaccines. Pt has been seen at clinic and a school for neurological problems and pt is also seeing an allergist.

Other Meds: Received DEPO PROVERA on same day 150mg

Lab Data:

History: PCN-hives

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Sep-2009	22-Sep-2009	0	30-Sep-2009	29-Oct-2009	CA		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Dizziness, Headache, Lip ulceration, Malaise, Oral mucosal eruption, Pyrexia, Respiratory tract congestion

Symptom Text: Severe headache - Dizziness - fever - cough - stuffy nose, general ill feeling, oral cavity mucose Mb and upper lips - erosive reaction - ulcer - still severe headache and dizziness.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359038-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Aug-2009	28-Aug-2009	0	01-Oct-2009	02-Oct-2009	FR	WAES0909USA03500	02-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1285U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Concussion, Convulsion, Fall, No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a gynaecologist concerning a 13 year old female patient who was vaccinated with the second dose of GARDASIL (Lot number 1285U and Batch number NH35150) IM into the left upper arm on 28-AUG-2009. The same day the patient developed syncope and "seizure symptoms" for 3 minutes. The patient felt down on the back of the head and experienced a commoti cerebri. The patient was hospitalized for observation (duration not reported). The patient recovered. The first dose of GARDASIL, administered in July 2009, was well tolerated. CASE IS CLOSED. Other business partner numbers included: E2009-08791.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 359039-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Dec-2008	01-Feb-2009	41	01-Oct-2009	02-Oct-2009	--	WAES0909USA03711	02-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	1	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Autoimmune thyroiditis, Blood test, Infectious mononucleosis, Streptococcal infection, Swelling, Weight increased

Symptom Text: Information has been received from the parents concerning their daughter, an 18 year old female patient with no pertinent medical history and drug reactions/allergies who intramuscularly received the first 0.5ml dose of GARDASIL (lot#660557/0072X) on 10-JUL-2008 and the second dose (lot#661531/1311X) on 22-DEC-2008. Concomitant therapy included SYNTHROID and CYTOMEL. It was reported that the first vaccination was given concomitantly with meningitis vaccine (manufacturer unknown). In February 2009, the patient has had 3 strep infections. On 10-APR-2009, the patient developed chronic mononucleosis. It was also reported that in approximately April 2009, the patient started "swelling up, developed hashimoto's thyroiditis, she has also gained 35-40 pounds". The patient has not been able to return to school this year. The patient's father reported that the patient was a "college athlete". The patient had sought unspecified medical attention. Unspecified blood work has been performed, but the result was not reported. At the time of the report, the patient was recovering. Swelling up, chronic mononucleosis, hashimoto's thyroiditis and 3 strep infections were considered to be disabling. A lot check has been initiated. Additional information has been requested.

Other Meds: SYNTHROID; CYTOMEL

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **359040-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		01-Oct-2009	02-Oct-2009	TN	WAES0909USA03751	02-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Gait disturbance

Symptom Text: Information has been received from a physician who "heard from a patient that someone related to her friend", a female, who was vaccinated with her second dose GARDASIL on an unspecified date. Subsequently the patient required assistance in walking. The patient might have been treated at a hospital. At the time of the report, the patient's status was unknown. Follow up information on 25-SEP-2009 has been received through a phone call from a physician. The physician stated that she did not know any information of the patient. She would ask the person who report the case to get the patient's adverse experience. Required assistance in walking was considered to be disabling. The Health Care Professional contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number (if applicable), lot number, date of event, recovery status, hospital name (if applicable), healthcare provider name and contact information. No further information is available at this time. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 359041-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Sep-2009	21-Sep-2009	0	01-Oct-2009	02-Oct-2009	--	WAES0909USA03759	02-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Facial bones fracture, Fall, No reaction on previous exposure to drug, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a Registered Nurse (R.N.) concerning a 11 year old female who on 21-SEP-2009 experienced a syncopal episode with tonic-clonic movements after receiving her second dose of GARDASIL (lot# 0216Y). It was reported that when she fell during this episode she fractured her nose. The patient sought medical attention and was seen by the nurse. X-rays of nose indicated fractured nose. The outcome was unknown. Follow up information was received from a Licensed Practical Nurse (L.P.N.) on 24-SEP-2009 via telephone reported that the patient with no pertinent medical history and allergic to AUGMENTIN (hives) was vaccinated with her second dose of GARDASIL (lot#0216Y) on 21-SEP-2009. No other vaccines and concomitant therapies were given that day. After fall, the patient was not sent to emergency room but for an x-ray of the nose and a CT of the head. Both revealed a nasal fracture. The patient's current status was recovering. She was referred to an ENT (name not provided) and surgery was planned. It was also reported that the patient was given the first dose of GARDASIL (lot# 662300/0100Y) in the left arm on 15-JUL-2009. Other vaccines given on that day included a dose of MENACTRA (lot# U2925AA) and a dose of VARIVAX (Oka) (lot# 0690Y). There was no problem after the first dose of GARDASIL. The reporter considered the fractured nose to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: head computed axial, nasal fracture; X-ray, nasal fracture

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359042-1 (S)** **Related reports:** 359042-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		01-Oct-2009	02-Oct-2009	PA	WAES0909USA04030	02-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Complex regional pain syndrome

Symptom Text: Information has been received from a physician concerning a 16 or 17 years old female who was vaccinated with a dose of GARDASIL. Subsequently the patient experienced reflex sympathetic dystrophy within 1 day of administration of the vaccine. The patient was hospitalized for 1 month. The name of the hospital, dates of hospitalization, or patient specific information was not available. At the reporting time the patient had not recovered. Reflex sympathetic dystrophy was considered to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **359042-2 (S)** **Related reports:** 359042-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	10-Aug-2007	01-Oct-2007	52	20-Oct-2009	21-Oct-2009	--	200904302	26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Complex regional pain syndrome, Muscular weakness, Pain

Symptom Text: Initial report was received 12 October 2009 from another manufacturer, report number WAES 0909USA04030. The initial reporter to this manufacturer had been a health care professional. This manufacturer also received follow-up information from a registered nurse, and the patient's mother. Verbatim from the report: "Information has been received from a physician concerning a 16 or 17 year old female who was vaccinated with a dose of GARDASIL. Subsequently the patient experienced reflex sympathic dystrophy within 1 day of administration of the vaccine. The patient was hospitalized for 1 month. The name of the hospital, dates of hospitalization, or patient specific information was not available. At the reporting time the patient had not recovered. Follow up information was received from the patient's mother and a registered nurse, the patient's mother reported the patient's date of birth and stated that the patient had no known drug allergies and had no significant medical history prior to the GARDASIL injection and was on no concomitant medications at the time of vaccination. The mother also stated that her daughter started to experience symptoms on 01-OCT-2007 and on 11-OCT-2007 she was diagnosed with reflex sympathic dystrophy and was hospitalized for 10 days as an inpatient. Upon her discharge the patient was treated with outpatient therapy (PT) from 8 am to 5 pm daily for left lower extremity weakness and pain associated with the reflex sympathic dystrophy. The patient's symptoms had not fully resolved, as the mother reported that she has "manageable flare-ups" which require PT and/or time at the gym, have occurred off and on since her disease onset to as recently as this school year. The registered nurse reported that GARDASIL was given on 10-AUG-2007 (Lot # 658282 / 0929U). The patient also received MENACTRA on the same date. The NP who is also the patient's mother noted that she was unsure of GARDASIL association with her daughter's experiences and will not have her daughter complete the series. Reflex sympath

Other Meds: Unknown

Lab Data: Not reported

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **359043-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-May-2009	06-Jun-2009	12	01-Oct-2009	02-Oct-2009	FR	WAES0909USA04195	02-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Case received from a physician on 22-SEP-2009 and additional information received on 24-SEP-2009. Information has been received from a physician concerning a 14 year old female patient with no relevant medical history except for classical infantile diseases who on 25-MAY-2009 was vaccinated with the first dose of GARDASIL (lot#, route and site of administration not reported). On 06-JUN-2009, she experienced a probable "a frigore" facial paralysis, with a massive motor deficit of the hemiface (the side was not specified). The patient consulted at the Emergency Unit Care. She was seen by the otorhinolaryngology service. No etiology was found. She recovered within one month. On 24-SEP-2009, it was confirmed that she had experienced a peripheral facial paralysis. Treatment was unknown. She recovered without sequelae. Facial paralysis was considered to be an other important medical event. Other business partner numbers included: E2009-08880. No further information expected.

Other Meds: Unknown

Lab Data: Unknown

History: General symptom

Prex Illness:

Prex Vax Illns:

Vaers Id: **359089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Oct-2009	01-Oct-2009	0	01-Oct-2009	12-Oct-2009	TX		23-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3015AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0087Y	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0973Y	1	Right arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B046BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonia

Symptom Text: Pt. received shots, stated she was "fine". Pt. told to sit in the blue chairs while mom checked out. Mom stated "she just went limp." Taken by w/c to back and laid down, legs moved & juice given.

Other Meds:

Lab Data:

History: Allergy: milk

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359106-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Mar-2009	01-May-2009	51	01-Oct-2009	28-Oct-2009	MI		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Madarosis

Symptom Text: Mother states that patient was losing eye brows and eye lashes starting 2 months after GARDASIL. The eyelashes and eye brows growing back. Mother states that patient is feeling flushed. But patient denies recovering.

Other Meds:

Lab Data: None

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359166-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
37.0	F	02-Oct-2009	02-Oct-2009	0	02-Oct-2009	12-Oct-2009	MD		12-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	98437P1A		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Heart rate decreased, Hyperhidrosis, Syncope

Symptom Text: Pt had a syncopal episode, fell and hit her head on the floor. Became diaphoretic, Pulse 80/palp, pulse 42. Immediately regained consciousness and was A&Ox3

Other Meds: Baraclude

Lab Data: EKG- Sinus bradycardia at 49bpm, otherwise normal

History: Hepatitis B, under treatment

Prex Illness: None

Prex Vax Illns:

Vaers Id: 359194-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		02-Oct-2009	05-Oct-2009	FR	WAES0909USA04481	05-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Diarrhoea, Epilepsy, Feeling of body temperature change, Headache, Myalgia, Nuclear magnetic resonance imaging normal, Postural orthostatic tachycardia syndrome, Somnolence, Unresponsive to stimuli

Symptom Text: Case received from a foreign health authority on 22-SEP-2009 under health reference no. PEI2009020328. It was reported that an at least a 16 year old (also reported as 15 year old) female patient with a disposition to orthostatic hypotension since years, was vaccinated with an unspecified dose of GARDASIL (lot number, injection site and route not reported) on an undefined date in 2007. Concomitant therapy included hormonal contraceptives (unspecified). About 2 or 3 weeks post vaccination the patient developed relapsing abdominal cramps following the same pattern: abdomen tensed and was very painful. She felt hot and cold and was unresponsive to stimuli with progression. Symptoms lasted for about 30 to 45 minutes respectively. Afterwards the patient was very sleepy. The following days the patient developed abdominal muscle ache, mild headache and diarrhea. On 11-AUG-2009 the patient was hospitalized due to increasing frequency (up to twice a month). Physical and neurological examination showed no pathological findings. Electrocardiography (EEG) on 11-AUG-2009 under hyperventilation showed intermittent bifrontotemporal focal retardation with repeating spikes on both frontal sides with changing emphasized sides. EEG after sleep deprivation on 12-AUG-2009 showed dysrhythmic groups, starting from frontal right, then generalized with spikes also frontal right. A cranial Magnetic Resonance Imaging had been previously carried out and was without pathological findings. Because of typically course of symptoms the patient was diagnosed with epilepsy with complex focal seizures. Treatment with lamotrigine was started. A Schellog test was carried out and showed a mild postural tachycardia syndrome. A blood sample (routine laboratory) was taken on 12-AUG-2009 and showed normal results except for C-reactive protein (6.5 mg/L; normal values 0.1-5.0). Upon reporting from dated 21-AUG-2009 the patient had not recovered at the time of reporting. The reporter assessed a possible temporal coincidence between vaccination and beginning

Other Meds: hormonal contraceptives (unspecified)

Lab Data: electroencephalography, 11Aug09, intermittent bifrontotemporal focal retardation with repeating spikes on both frontal sides; electroencephalography, 12Aug09, EEG after sleep deprivation on 12-AUG-2009 showed dysrhythmic groups; serum C-rea

History:

Prex Illness: Orthostatic hypotension

Prex Vax Illns:

Vaers Id: **359195-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Aug-2009	28-Aug-2009	0	02-Oct-2009	05-Oct-2009	FR	WAES0909USA04482	05-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DT	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Electrocardiogram normal, Immediate post-injection reaction, Loss of consciousness, Neurological examination normal, Syncope, Tonic clonic movements

Symptom Text: Initial information was received on 24-AUG-2009 by the Foreign health Authority (Reference number ES-AGEMED-220130444) regarding a 14 year old female who was administered on 28-AUG-2009 a dose of GARDASIL (lot number, injection site and not reported) by intramuscular route. On the same date the patient also received a dose of DITANRIX by intramuscular route, site not reported. Immediately after vaccine administration with GARDASIL and DITANRIX, the patient presented vasovagal syncope with loss of consciousness that lasted for one minute, also the patient presented orofacial tonic clonic movements which lasted a few seconds. The patient recovered spontaneously that same day, 28-AUG-2009. Neurologic exploration, glucemic exploration and electrocardiogram were all normal. The patient has a medical history of syncopes without loss of consciousness. Case reported as serious by the health authority with other medically important condition as criteria. Other business partner numbers include E200908954.

Other Meds: Unknown

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359206-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	22-Sep-2009	25-Sep-2009	3	02-Oct-2009	12-Oct-2009	MA		12-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Palpitations

Symptom Text: significant anxeity with palpitations 3 days following 3rd infection. No prior hx of anxiety or mental illness. No alcohol or substance use. Slowly improving now 10 days post injection

Other Meds: loovral

Lab Data: normal tsh and cbc

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **359263-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Sep-2009	19-Sep-2009	3	03-Oct-2009	13-Oct-2009	GA		07-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3209AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Blood test normal, Heart rate increased, Incoherent, Loss of consciousness, Skin discolouration, Syncope

Symptom Text: Syncope - Running a 5K, child is a half marathoner and 5K state champion. Pulse went to 172. Ash gray in face and memory loss of event. This had never happen before, occurred again on 10/3/2009. Emergency room, doctor ran EKG and ECO showed nothing. 10/28/2009 records from Cardiologist and PCP for dates 9/22/2009 and 10/13/2009. Patient presented with sx of syncope, incoherent speech, paleness, and "passing out" while running a marathon on 9/19/2009. Cardiac workup was negative. Patient saw new PCP 10/13/2009, asymptomatic at this time. Further dx tests were ordered.

Other Meds:

Lab Data: Blood work, sugar level check, EKG and ECO all negative. Labs: CBC, CRP, CMP, complement studies, ANA profile, ESR, TSH, Ferritin WNL Dx tests: Echo, Holter monitoring, EKG WNl

History: None PMH: Anorexia Nervosa, Amenorrhea Allergies: NKDA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **359280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Sep-2009	29-Sep-2009	1	02-Oct-2009	29-Oct-2009	MA		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Gait disturbance, Pain in extremity

Symptom Text: Positive leg pains, feels weak and unable to walk straight.

Other Meds: AVIA

Lab Data: CBC; CRP; CK; CMP

History: Allergies to some foods

Prex Illness: None

Prex Vax Illns:

Vaers Id: **359334-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	14-Jul-2009	21-Jul-2009	7	05-Oct-2009	15-Oct-2009	--		19-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	9725103		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Headache, Heart rate irregular, Hypoaesthesia, Oropharyngeal swelling

Symptom Text: Headaches & right upper extremity numbness after GARDASIL. ```MR received on 01/08/10 for DOS 07/14/09. Pt presented for routine physical. Pt with oropharyngeal edema, erythema, TM clear. Irregular HR. Pt c/o HA, numbness in BUE right after vaccination. On 10/01/09 Pt was seen again and no improvement. Decision was made to stop Gardasil series. Pt did not show up for F/U appts. ```Vaccine record received on 01/14/10

Other Meds:

Lab Data: None

History: ```PMH: Head trauma in 2008, SAB in 2004, cycles irregular, positive PPD, LEEP, D&C 2007; Allergies: PCN, seasonal allergies, INH hives, HPV.

Prex Illness:

Prex Vax Illns:

Vaers Id: **359336-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Sep-2009	28-Sep-2009	0	05-Oct-2009	12-Oct-2009	--		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Confusional state, Dizziness, Gait disturbance, Headache, Immediate post-injection reaction, Nausea, Pallor, Posture abnormal, Vaccination complication, Vision blurred

Symptom Text: GARDASIL first shot - immediately after receiving shot, patient turned grey. Within half an hour of receiving the shot, patient was dizzy, confused, light headed, severely nauseous, reported blurry vision, had gait dysfunction, appeared "stoned", and was unable to hold her head up straight. This continued throughout the day -shot was administered at 11:30am-. Primary doctor was contacted and indicated this was and adverse reaction to the GARDASIL shot. At approx 5pm - I - the patient's mother- decided it was time to to to the ER. Took patient to ER, diagnosis of adverse vaccine reaction was confirmed, manufacturer was contacted -merck-, and ER doctor confirmed with Merck that generally these reactions do not progress beyond the point where patient was in reaction. Patient was released after observation of vitals and neurological responses. 10/6/09 ER records received for 9/28/09. DC DX: Vaccine reaction, Dizziness, HA. Presenting SX: pt went to ER with c/o dizziness, headache, blurred vision after gardasil vaccine same day. Assessment: onset of dizziness 8 hours prior to ER, at time of ER visit sx improving. PE WNL.

Other Meds:

Lab Data: 10/6/09 ER records received for 9/28/09. Diagnostics/Labs: accucheck WNL.

History: 10/6/09 ER records received for 9/28/09. lactose intolerant.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Aug-2009	12-Aug-2009	0	05-Oct-2009	15-Oct-2009	UT		15-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Patient experienced brief loss of consciousness and seizure 1/2 hr after GARDASIL in car on way home. Episode lasted less than 1 minute. Waited in medical office 20 minutes after injection before driving home without incident.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359398-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Aug-2009	20-Aug-2009	2	05-Oct-2009	15-Oct-2009	NJ		23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Received GARDASIL shot on 8/18/09. Developed hives on 08/20/09 w/c lasted 2 days and an ED visit on 8/21/09.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **359445-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Sep-2009	03-Sep-2009	0	05-Oct-2009	06-Oct-2009	FR	WAES0909USA00612	06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ29430	2	Left arm	Intramuscular	
	HEP	MERCK & CO. INC.	1422U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Epistaxis, Fatigue, Headache, Malaise, Musculoskeletal chest pain, Oropharyngeal pain, Paraesthesia, Presyncope

Symptom Text: Information has been received from a health professional concerning a 12 year old female patient who on 03-SEP-2009 was vaccinated with a dose of GARDASIL. Secondary suspect vaccine given on the same day included RECOMBIVAX HB. It was reported that the patient developed "non stop nose bleeding" on the day of vaccination, 03-SEP-2009. It was reported that the patient had not recovered at the time of reporting. Additional information has been received from a nurse concerning a 12 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL and the first dose of RECOMBIVAX HB, the patient experienced a vaso-vagal episode. After the second dose of GARDASIL the patient had no adverse event. 03-SEP-2009 the patient was vaccinated with the third dose of GARDASIL (lot number: NJ29430, Batch number: NJ20450) intramuscularly in the left arm and the second dose of RECOMBIVAX HB (lot number, 1422U, Batch number: NJ11300) intramuscularly in the left arm at approximately 10:00 am at school. On the same day after vaccination, the patient had a nose bleed 2 hours after immunization. The nose bleed took 20 minutes to stop. The patient also complained of "tingling" sensation in her left arm all day. The "tingling" sensation continued until the next day when it resolved with no treatment. The patient also complained of headache, dizziness and fatigue, the patient had another nosebleed over night 14 hours later from vaccination, which took 20 minutes to stop. On the next day the patient still felt unwell, stayed home from school. The patient also complained of sore ribs and sore throat. The patient was taken to her general practitioner on 04-SEP-2009 at 1:00 pm. The general practitioner believed the patient's symptoms were unrelated to GARDASIL and RECOMBIVAX HB. The general practitioner concluded that the patient had a virus prior vaccination which resolved over 2-3 days following visit to general practitioner. The patient confirmed that she had felt unwell for the 2 days prior to immunization.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Viral infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359446-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		05-Oct-2009	06-Oct-2009	--	WAES0909USA03644	06-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Blindness transient

Symptom Text: Information has been received from a physician, that was informed by a patient, that someone else experienced temporary blindness within one or two days after receiving the second 0.5 ml dose of GARDASIL. The pt was reported to be female between 16 and 18 years old. No further information was provided. The physician was not the treating physician of this patient and does not wish to be contacted regarding this case. The reporting physician considered temporary blindness to be disabling. Attempts to verify the existence of an identifiable patient have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **359467-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-Oct-2009	01-Oct-2009	0	05-Oct-2009	15-Oct-2009	TX		15-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0980Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Fatigue, Nausea, Vomiting

Symptom Text: Patient received Gardasil vaccine dose #2 on 10/1/2009, and that evening she complained of chills, nausea, and several episodes of vomiting. She reports no fever, and her symptoms resolved that night. She does report feeling fatigued for the next 24 hours after the onset of her symptoms but reports no futher complaints.

Other Meds: Necon 777 oral contraceptive

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359479-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	24-Jul-2009	26-Jul-2009	2	05-Oct-2009	15-Oct-2009	TX		15-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0455Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Nausea, Pain

Symptom Text: Patient reports going to a hospital ER 2 days after receiving Gardasil vaccine dose #1 due to complaints of body aches, chills, and nausea. She states she was not diagnosed with any specific conditions and was told to take ibuprofen and go home and rest. She reports no current complaints and did not inform our office of this event until today.

Other Meds: Tindamax 500 mg #10 was prescribed on 7/24/2009.

Lab Data: unknown

History: bacterial vaginosis

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359491-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Aug-2009	18-Aug-2009	0	05-Oct-2009	15-Oct-2009	MS		15-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Gaze palsy, Hypotonia, Loss of consciousness, Moaning, Pallor, Syncope, Unresponsive to stimuli

Symptom Text: She was standing and began to feel weak then fainted and was completely unconscious for a few minutes. She turned completely white her eyes rolled upward and she was moaning. She could not respond for a few minutes and was completely limp.

Other Meds:

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359514-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Oct-2009	03-Oct-2009	0	05-Oct-2009	29-Oct-2009	AZ		02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Malaise

Symptom Text: Rec'd shot in L arm and states feel "sick" lightheaded-protected on chair lowered head & knees -encouraged to take deep deep breaths- Mom @side. Stated this always happens "she'll be fine" assisted to BR per request. Mom @ side helped to toilet seat, voided, cool cloths to back if sick. "I want to go home"- Mom went to get car stayed with pt. assisted safely to car encouraged to call prn for assist 1330 called LMom if any questions call prn. a take to family dr. a ER if concerns.

Other Meds: Denies

Lab Data: NA

History: Denies

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359553-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Aug-2009	07-Sep-2009	7	06-Oct-2009	16-Oct-2009	MA		11-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Compartment syndrome, Exercise tolerance decreased, Intervertebral disc protrusion, Muscular weakness, Myositis, Pain in extremity

Symptom Text: 1 week after GARDASIL vaccine 8/31/09, pt started feeling migratory pain in her legs and weakness. Her running stamina has decreased, and she ever feels weak when she climbs stairs. Exam nl. Temp 97.6. NL DTRs, sensation, strength in legs.10/9/2009 MR from PCP received office visit 10/2/2009. Presenting c/o's of pain and weakness in legs, sx x 4 weeks. PE was normal. DX: compartment syndrome, myositis, herniated disc syndrome. Referred to Orthopedic MD. 10/12/09 Per parent pt has not been to see any consult. Still having some weakness.

Other Meds: ADVIL

Lab Data: None yet Lab: none Dx studies: none

History: None + Amoxicillin allergy PMH: none

Prex Illness: None

Prex Vax Illns:

Vaers Id: **359618-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Jun-2009	30-Jun-2009	0	06-Oct-2009	07-Oct-2009	CA	WAES0910USA00004	06-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0478Y		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0558X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Grand mal convulsion, Irritability, Limb discomfort, Loss of consciousness, Palpitations, Syncope, Tremor, Viral infection

Symptom Text: Information has been received from a consumer concerning her 15 year old female daughter with stomach surgery (when she was 5 years old), who at the end of June 2009 (approximately 30-JUN-2009) was vaccinated with the first dose of GARDASIL (Lot number not provided). There was no concomitant medication. The consumer reported that on approximately 30-JUN-2009 "within a minute of receiving the first dose of GARDASIL" the patient collapsed and her arms started jerking around. The patient was brought to the emergency room but she was not admitted. The patient went home the same day. The consumer reported that the patient had been experiencing shakes and heart palpitations for 3 to 4 weeks starting on approximately 02-SEP-2009. Therapy with GARDASIL was discontinued (date not specified). At the time of the report the patient had not recovered. The patient sought medical attention at the physician. Upon internal review collapsed and her arms started "jerking around" were determined to be an other important medical event. Additional information has been requested. 10/26/09 Medical records received for date 6/18/09. Pt c/ reaction after receiving varivax #2, and gardasil #1. c/o tonic clonic seizure after vaccine. bhp 12/29/2009 ER record received for DOS 06/18/2009. DX: Syncope Patient presented to ER feeling well with no weakness or sensory deficits. Patient reported that after receiving a vaccination, her arm was hurting. Upon receiving a second vaccination in her other arm, the patient passed out for twenty seconds with jerking movements in arms and legs. When patient came to, she was alert and not confused. Discharged home. 01/04/2010 hospital records and clinic notes received for DOS 11/22/1993-10/23/2009. DX: Fainting spells, Syncope following Gardasil, Viral Syndrome Clinic note of 06/18/2009 notes patient was observed in office post seizure and given glucose wafer because last meal was approximately 6 hours earlier. Clinic note of 09/23/09 notes complaint of fainting spells and plan/treatment no

Other Meds: None

Lab Data: 12/29/2009 Diagnostics: Accu-Chek-116 (range: 70-105), EKG- sinus bradycardia with rate of 52. No ST or T wave abnormalities and no ectopy. Intervals are normal./rem

History: Gastrointestinal surgery 01/04/2010 PMH: Hypoglycemia, Dumping Syndrome, Fundoplicatons X3, Deviated nasal septum, sleep disorder and chronic cough.

Prex Illness:

Prex Vax Illns:

Vaers Id: 359619-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Nov-2008	20-Mar-2009	127	06-Oct-2009	07-Oct-2009	FR	WAES0908USA02600	07-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria aquagenic

Symptom Text: Information has been received from a physician via CSL as part of a business agreement (manufacturer control # 20090817JZ1) concerning a 13 year old female who on 13-NOV-2008 was vaccinated with her third dose of GARDASIL (lot number, route and site not reported). In the beginning of March 2009, the patient developed aquagenic urticaria, an allergy to water, which was ongoing. Additional information has been received from a physician concerning a 13 year old female patient who on 13-NOV-2008 (Also reported as October 2008) was vaccinated with the third dose of GARDASIL. No concomitant medication. On 20-MAR-2009, four months after vaccination, the patient developed a severe urticaria on contact to water (aquagenic urticaria). A normal blood screen was performed on 2009. At the time of reporting on 24-SEP-2009, the patient's aquagenic urticaria was slowly resolving. The physician considered aquagenic urticaria to be as other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: hematology, ??09, Normal blood screen

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **359620-1** **Related reports:** 359620-2; 359620-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Sep-2006	01-Sep-2009	1096	06-Oct-2009	07-Oct-2009	MI	WAES0909USA04206	14-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Blindness transient, Immediate post-injection reaction

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with no drug reactions/allergies who was vaccinated IM with the first 0.5 ml dose of GARDASIL "approximately three years ago" in approximately September 2006. Concomitant therapies included MENACTRA and another vaccine (manufacturer unknown). Right after getting the vaccine the patient experienced anxiety and temporary loss of vision. The patient was at the office when it happened. There were no lab diagnostic studies performed. The physician told the patient to remain seated for 10 to 15 minutes and the patient recovered. Upon internal review, temporary loss of vision was determined to be an other important medical event. All telephone attempts to obtain follow-up information have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **359620-2** **Related reports:** 359620-1; 359620-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Sep-2006	01-Sep-2006	0	09-Oct-2009	12-Oct-2009	--	200904187	24-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Blindness transient, Immediate post-injection reaction

Symptom Text: Initial report was received 05 October 2009 from another manufacturer; report # WAES 0909USA04206. The initial reporter to this manufacturer had been health care professional. Verbatim from the report: "Information has been received from a physician concerning a 14 year old female patient with no drug reactions/allergies who was vaccinated IM with the first 0.5 ml dose of GARDASIL "approximately three years ago" in approximately September 2006. Concomitant therapies included MENACTRA and another vaccine (manufacturer unknown). Right after getting the vaccine the patient experienced anxiety and temporary loss of vision. The patient was at the office when it happened. There were no lab diagnostic studies performed. The physician told the patient to remain seated for 10 to 15 minutes and the patient recovered. Upon internal review, temporary loss of vision was determined to be an other important medical event. All telephone attempts to obtain follow-up information have been unsuccessful. No further information is available." Documents held by sender: None.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **359620-3** **Related reports:** 359620-1; 359620-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Sep-2006	01-Sep-2006	0	11-Mar-2010	18-Mar-2010	--	200904187	18-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Blindness transient, Immediate post-injection reaction

Symptom Text: Initial report was received on 05 October 2009 from another manufacture; report # WAES 0909USA04206. The initial reporter to this manufacturer had been a health care professional. Verbatim from the report: "Information has been received from a physician concerning a 14 year old female patient with no drug reactions/allergies who was vaccinated IM with the first 0.5 ml dose of GARDASIL "approximately three years ago" in approximately September 2006. Concomitant therapies included MENACTRA and another vaccine (manufacturer unknown). Right after getting the vaccine the patient experienced anxiety and temporary loss of vision. The patient was at the office when it happened. There were no lab diagnostic studies performed. The physician told the patient to remain seated for 10 to 15 minutes and the patient recovered. Upon internal review, temporary loss of vision was determined to be an other important medical event. All telephone attempts to obtain follow-up information have been unsuccessful. No further information is available." Documents held by sender: None.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359621-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		06-Oct-2009	07-Oct-2009	--	WAES0909USA04238	07-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Memory impairment, Urinary incontinence

Symptom Text: Information has been received from a nurse concerning a 14 year old female patient who was vaccinated IM with the first 0.5 ml dose of GARDASIL. There were no concomitant therapies. Subsequently the patient passed out and started seizing, the patient experienced a full blown seizure, blacked out, could not hold her bladder and then came to and could not remember anything that had happened. The patient was in office while it happened. At the time of report the patient's status was recovered. Upon internal review, seizure was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 359622-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Jan-2008	29-Mar-2009	452	06-Oct-2009	07-Oct-2009	NC	WAES0909USA04548	11-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Gallbladder operation, Pancreatitis acute

Symptom Text: Information has been received from a Registered Nurse concerning her 16 year old daughter who on 29-JUN-2007 was vaccinated with a first dose of GARDASIL (lot # not reported). On 29-AUG-2007 she received second dose of GARDASIL (lot # not reported). On 02-JAN-2008 she received third dose of GARDASIL (lot # not reported). On 29-APR-2009 the patient experienced acute pancreatitis and was hospitalized. On an unspecified date the patient recovered from acute pancreatitis. Laboratory test revealed: Amylase level: 3200 and lipase level 2000. Follow up information has been received on 30-SEP-2009 via telephone call from Medical Assistant (the patient's mother) (previously reported as Registered Nurse). The Medical Assistant stated that her daughter received first dose of GARDASIL (lot # 657736/0389U) on 29-JUN-2007. On 29-AUG-2007 she received second dose of GARDASIL (lot # 657736/0389U). On 02 - JAN-2008 (previously reported as 02-JAN-2007) she received third dose of GARDASIL (lot # 659055/1522U). The patient did not receive any concomitant vaccinations when GARDASIL vaccinations were administered. The Medical Assistant stated that the patient experienced abdominal pain on 29-MAR-2009. The patient was taken to the hospital but was not admitted. Later that day, the patient was taken to other hospital. The patient was admitted with complaint of abdominal pain on 29-MAR-2009 (previously reported as 29-APR-2009) and was diagnosed with acute pancreatitis. The patient was discharged on 01-APR-2009. The patient had recovered. The name of the Primary Care physician was provided. The patient complained of abdominal pain, (date not reported). In May 2009 the patient had her gall bladder removed (hospitalization dates unknown to reporter). On an unspecified date the patient recovered. On 31-AUG-2009, the patient complained of abdominal pain and was taken to the hospital. The patient's blood tests (test unspecified) were normal. The patient was not admitted to the hospital. The Medical Assistant stated that the patient had experie

Other Meds: Unknown

Lab Data: diagnostic laboratory 08/31/09, Blood tests were normal; serum amylase test, 03?/??/09, 3200; serum lipase test, 03?/??/09, 2000 01/07/10 and 01/08/10 MR and DC summary received for DOS 03/29/09-04/01/09. DX studies: no electrolyte abnor

History: PMH: none; Allergies: NKDA.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359683-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Sep-2009	26-Sep-2009	2	06-Oct-2009	16-Oct-2009	MO		22-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Headache

Symptom Text: Seizure on 09-26-09. 10/15/2009 received hospital records for date 9/27/2009. Patient left hospital approx 2 hours later without seeing MD or getting any Tx. 10/15/09: Hospital records receiced for date of service 9/27/09 Assessment: Pt. presented with HA pain 4/10. VSS, left before seeing MD. No mention of seizure in records. 10/16/2009 received Immunization Records.

Other Meds:

Lab Data:

History: Migraines PMH: migraines Allergies: NKDA

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359684-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Sep-2009	22-Sep-2009	0	06-Oct-2009	16-Oct-2009	KS		16-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041CA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0810Y	0	Left arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB327AA	0	Right arm	Intramuscular	
MNC	WYETH PHARMACEUTICALS, INC	U3021AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0213Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breath holding, Nausea

Symptom Text: Pt states she felt she was going to throw up and doesn't remember anything else. Pt states she was holding her breath. Pt states she feels fine this time. Pt states she may have passed out, unwitnessed.

Other Meds:

Lab Data:

History:

Prex Illness: Cough, runny nose, no temp

Prex Vax Illns:

Vaers Id: **359737-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Sep-2009	24-Sep-2009	1	06-Oct-2009	19-Oct-2009	CA		19-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	AHAVB326AA	1	Left arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B046DA	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0653X	0	Left arm	Unknown	
FLUN	MEDIMMUNE VACCINES, INC.	500677P		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Lethargy, Pain

Symptom Text: 16yo female who presented 7 days after vaccine with 4-6 d of body aches, lethargy and initiation of headaches (Hx of stress associated H. A. C in past) - No physical or labs findings.

Other Meds:

Lab Data:

History: Stress related headaches

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359739-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Sep-2009	25-Sep-2009	1	06-Oct-2009	29-Oct-2009	CA		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U0360AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0216Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling, Pruritus, Swelling face

Symptom Text: Pt received HPV & MENINGOCOCOAL AT 7:40 PM ON 9/24/09 16 hrs post shot c/o itchy face & face was swollen - 24 hrs post shot eyes swollen completely shut & face swollen. BENADRYL given.

Other Meds: ADERALL XR 25

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **359747-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Oct-2009	02-Oct-2009	0	07-Oct-2009	19-Oct-2009	IN		21-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	06 72Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acne, Dizziness, Dyskinesia, Heart rate increased, Hypoaesthesia, Mood swings, Paraesthesia, Reflux oesophagitis, Tachycardia

Symptom Text: Ashley complained of fast heart rate, dizziness, numbness and tingling in hands and feet. 10/12/09 Medical records received from dates of service 10/2/09 to 10/8/09 10/2/09 OV for c/o ball in throat feeling, acne, hair loss and to begin gardasil vaccination series. DX: questionable reflux, acne, hair loss. 10/8/09 OV c/o HA, dizziness, moody, heart racing, jerking arms, tingle in fingers occurring after getting gardasil vaccination. DX: HA, dizziness, tachycardia.

Other Meds: Buspar

Lab Data: Saw her therapist and talked with her psychiatrist. 10/2/09 Labs: TSH WNL, CBC WNL. 10/8/09 Labs: Influenza A(-) B(-).

History: General anxiety disorder 10/2/09 MH: Anxiety disorder

Prex Illness: Feel has a Ball in throat. History hair loss but regrowing hair.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359768-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Aug-2009	15-Aug-2009	2	06-Oct-2009	29-Oct-2009	NC		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	03124	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives all over body per ER visit on 8-15-09.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **359778-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-Sep-2009	16-Sep-2009	1	06-Oct-2009	20-Oct-2009	PA		20-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Rash macular

Symptom Text: Pink macular rash trunk & extremitary. Seen in ER 9-16-09. Treated with DECANDRON and BENADRYL. Sent home in MEDROL dose pak.

Other Meds: NAPROXYN

Lab Data: Pt was also taking NAPROXEN when rash developed.

History: Allergic to CEDOR.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 359858-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jul-2009	07-Jul-2009	5	07-Oct-2009	08-Oct-2009	OH	WAES0907USA00374	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1131X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Amenorrhoea, Autoimmune thyroiditis, Decreased appetite, Diarrhoea, Dizziness, Fatigue, Haematuria, Headache, Influenza like illness, Local swelling, Lymphadenitis, Lymphadenopathy, Malaise, Nausea, Oropharyngeal pain, Pollakiuria, Pyrexia, Urinary tract infection, Urticaria

Symptom Text: Information has been received from a physician concerning a female who on 02-JUL-2009 was vaccinated intramuscularly with a dose of GARDASIL (lot no. not reported). After vaccination, on an unknown date, the patient started experiencing flu like symptoms and had swelling in her groin area. Subsequently, the patient recovered. Follow up information has been received from a licensed practical nurse who regarding a 17 year old female at 134 pounds weight and 52 inches with drug allergies to AUGMENTIN, OMNICEF, BACTRIM who on 02-JUL-2009 was vaccinated intramuscularly in the right deltoid with her first dose of GARDASIL (Lot#661954/1131X) at 11:50 am. It was reported that 5 - 7 days following GARDASIL first injection on 07-JUL-2009, the patient experienced cervical lymphadenopathy, sore throat, headache, dizziness, fever (TM 102.3), hives, nausea, diarrhea and loss of appetite. On an unknown date some symptoms dissipated but the patient had prolonged (10 weeks) of out cervical lymphadenopathy, fatigue and dizziness. Extensive work-up by a hematologist, ENT (ears, nose, and throat), infectious disease and endocrinology. At the time of the report the patient was improving. the liscensed practical nurse considered the patient's experience to be disabling. Additional information has been requested. 10/19/2009 records from PCP, ENT, Hematologist and Endocrinologist visits. Patient 5 days post vaccine had sx of: cervical lymphadenopathy, headache, sore throat, fever, urticaria, nausea, diarrhea, dizziness , malaise, fatigue and anorexia. Initially dx'd with strep pharyngitis and was on ABX x 2 and Medrol dose pak, lymph node size decreased at first but then rebounded and have continued to enlarge since then. PE notes tender , mobile bilateral enlarged cervical lymph nodes appox 2-3 cm. ED visit 9/10/2009: sx frequent urination, hematuria. DC Dx UTI, Tx'd with ABX/Pyridium. Final Dx: Hashimoto's Thyroiditis, Viral lymphadenitis with mono-like illness. Tx: modify activities/rest. 11/5/2009 records from OB-GYN MD

Other Meds: Unknown

Lab Data: oral T, 102.3 Lab: CBC, Lipid profile, CMP, LDH, ESR, CMV titer, IgM titer, Toxoplasmosis serology WNL, TSH 5.1 high, Cat scratch panel. Mono-test, PPD, EBV, ANA negative, ACE normal, Monocyte ct 15.6 high, Basophil ct high at 2.05, Thyro

History: PMH: Migraines, Asthma Allergies: Amoxicillin, Augmentin, Omnicef, Sulfa

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **359859-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Jan-2009	22-Jan-2009	0	07-Oct-2009	08-Oct-2009	MA	WAES0909USA04933	29-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	9000		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1311X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Asthma, Back pain, Drug exposure during pregnancy, Foetal disorder, Premature labour, Urinary tract infection

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female with no known drug reactions/allergies and severe asthma who on 15-APR-2008 was vaccinated intramuscularly with the first dose of GARDASIL (Lot # 659964/1978U) and on 22-JAN-2009, was vaccinated intramuscularly with the second dose of GARDASIL (Lot # 661531/1311X). Concomitant therapy included ADVAIR, FLOVENT, Prednisone, Albuterol and Influenza virus vaccine (unspecified) (given on 22-JAN-2009). The registered nurse reported that the patient became pregnant after receiving the second dose of GARDASIL. She also stated the patient delivered the baby on 11-SEP-2009; however, the baby was born with hydrocephalus. The patient sought unspecified medical attention. On 01-OCT-2009, through a telephone call, the registered nurse reported that the mother and baby were being treated by the same physician. The mother was seen in the office on 22-JAN-2009 for an appointment. She was a severe asthmatic who had been on ADVAIR for years (exact therapy dates not provided) and ADVAIR was not controlling her asthmas as well as the physician would have liked. The patient was also noted to be a smoker. On 22-JAN-2009, the patient was switched to FLOVENT, Prednisone and Albuterol for asthma management. The patient was also given a flu vaccine (manufacturer not specified) and her second dose of GARDASIL. The registered nurse further noted that on that date (22-JAN-2009) the patient had a negative urine HCG test. It was estimated that the patient was actually 3 weeks, pregnant at the time of the urine pregnancy screen because she soon found out she was pregnant and her last menstrual period was estimated to have been around 02-JAN-2009. The reporter did not have the mother OB/Gyn contact information or any specific information surrounding her labor and delivery. She reported that she thought that the baby's hydrocephalus was diagnosed by ultrasound prior to his birth, but she did not have the baby's chart available at the moment to consult. She did re

Other Meds: albuterol; FLOVENT; ADVAIR; prednisone

Lab Data: Beta-human chorionic, positive; Beta-human chorionic, 01/22/09, negative . Labs & Diags: Fetal U/S- 19 wks, significant hydrocephalus and dilated lateral ventricles, thin cortical mantles, and dangling choroids. fetal U/S 22wks- moderate

History: PMH: Asthma. Previous normal full-term vaginal birth in 2007. Family h/o hydrocephalus, diabetes and hypertension. Allergies: NKDA

Prex Illness: Pregnancy NOS (LMP = 1/2/2009); Asthma; Smoker

Prex Vax Illns:

Vaers Id: **359860-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	04-Oct-2007	Unknown		07-Oct-2009	08-Oct-2009	FR	WAES0910USA00302	08-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Juvenile arthritis

Symptom Text: Case received from Health Authority on 29-SEP-2009 under HA reference no. PEI2009021046. It was reported that a female patient with medical history (no information reported) who was vaccinated with two doses of GARDASIL (lot #, injection route and site not reported) 04-OCT-2007 (also reported as 04-DEC-2007) and 31-JAN-2008. On an unspecified date, the patient developed juvenile idiopathic seropositive polyarthritis. The course of disease was chronic and the patient received unspecified medicinal treatment. Juvenile chronic polyarthritis was reported to be other important medical event. Other business partner numbers include E2009-09132. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 359892-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-May-2008	01-Feb-2009	261	07-Oct-2009	09-Oct-2009	WA		13-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	3	Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Anaemia, Asthenia, Cardiac monitoring, Chest pain, Dizziness, Dyspnoea, Electrocardiogram QT prolonged, Fatigue, Headache, Heart rate irregular, Menorrhagia, Oligomenorrhoea, Palpitations, Paraesthesia, Syncope, Thrombosis, Tinnitus, Vaginal haemorrhage, Vision blurred

Symptom Text: Started having severely long menstural cycle that lasted up to 6weeks and large blood clotting, now she's had what I feel are TIA's or what doc feels fainting spell, but most recently she's seeing a cardiologist her heart has started beating irregular beats and she's wearing a heart monitor. 1/11/10: ED Records received for date of service 7/17/09: Already received and abstracted. 10/8/09 Medical records received from PCP for dates 4/30/08 to 10/2/09. Routine PE exam 4/30/08 WNL, received first of three doses of gardasil. OV from 7/9/09 DX: Menorrhegia 7/17/09 DX: severe anemia, menorrhegia, palpitations, abnormal ECG, dizziness and visual disturbance. Presenting symptoms: Pt went for general PE 4/08 and received gardasil vaccine 1 of 3 final dose was given 11/08. On 7/9/09 pt c/o heavy menses. 7/17/09 pt c/o continued heavy menses, dizziness, tired, HA, weakness, slight shortness of breath, palpitations. 10/2/09: pt f/u appt from ER and cardiac consult with possible DX of long QT syndrome. ICD9 codes: 278.0, 286.9, 626.2, 794.31, 780.4, 368.8 12/30/2009 ED records for visit 7/17/2009 patient with c/o's excessive vaginal bleeding. Impression: Menorrhagia 12/30/2009 Ed records for 9/28/2009 patient with c/o's heart palpitations, chest pain, Impression: syncope 01/06/10 Cardiology notes received for 10/01/09. DX: borderline prolonged QT interval. Pt evaluated for dizziness, vision blurry, ears ringing, face going numb, nausea. Pt reported h/o stabbing chest pain q2mos. ECG: normal, ECHO: normal. Pt to return for exercise study. Cardiology notes received for 10/05/09. DX: borderline prolonged QT interval. Pt underwent an exercise stress test. Pt had increased heart rate, one premature ventricular contraction. Pt did not loose consciousness. ECG was done and normal, except QT prolonged. Pt placed in transtelephonic event monitor to capture supraventricular tachycardia related to preexcitation.

Other Meds: none previously but now on iron

Lab Data: She's still seeing a few doctors, I want to know if other families noticed changes. Patient has always been a very healthy girl with no previous health issues until her last shot of Gardasil was administrated to her. 10/8/09 Medical recor

History: none 10/8/09 Medical records received from PCP for dates 4/30/08 to 10/2/09. PMH: Obesity, Allergic Rhinitis, Tonsillectomy, Adenoidectomy, Uvulectomy. Allergies: NKDA

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359924-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Sep-2009	03-Oct-2009	5	07-Oct-2009	19-Oct-2009	KS		19-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0810Y	1	Left arm	Unknown	
IPV	SANOFI PASTEUR	B0476	1	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0087Y	1	Right arm	Unknown	
HEP	MERCK & CO. INC.	1445X	2	Left arm	Unknown	
FLU	SANOFI PASTEUR	U3174EA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous

Symptom Text: 9-28-09 Patient received vaccines. 10-03-09 Patient miscarried/spontaneous abortion at ER. She was 6 weeks pregnant.

Other Meds:

Lab Data:

History:

Prex Illness: Pregnant

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **359960-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Oct-2009	06-Oct-2009	1	07-Oct-2009	20-Oct-2009	MA		20-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC25B045CA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3055AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Myalgia, Paraesthesia, Vision blurred

Symptom Text: Muscle pain / tingling sensation throughout L leg dizziness and blurred vision.

Other Meds: None

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: 360039-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	04-Feb-2009	Unknown		08-Oct-2009	09-Oct-2009	--	WAES0906USA05698	15-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1496X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Intra-uterine death

Symptom Text: Initial and follow-up information has been received from Merck Pregnancy Registry for GARDASIL from a Nurse Practitioner concerning a 25 year old female patient with a history of 3 full term delivery pregnancies who on 03-DEC-2008 was vaccinated with a first dose of GARDASIL (lot # 661703/0651X) 0.5ml, intramuscularly. On 04-FEB-2009 she received second dose of GARDASIL (lot # 661954/1496X) 0.5ml, intramuscularly. There was no concomitant medication. The patient was pregnant. Pregnancy was discovered on test performed at the office before administering the third dose of GARDASIL when the patient reported missing a period. The patient had last menstrual period on 16-APR-2009. Estimate date of delivery is on 21-JAN-2010, but is subject to change with ultrasound schedule for the near future. On 16-JUL-2009, ultrasound was performed resulting 11 weeks and estimate date of delivery was changed to 04-FEB-2010. Follow up information has been received from a health care professional concerning a female patient with no concurrent medical conditions and no infections or illness during pregnancy who on12-SEP-2009 experienced a complication during pregnancy of fetal demise at 15 weeks. On an unspecified date serum alpha-fetoprotein test (AFP) was performed and showed increased risks of Down's. On 12-SEP-2009 (15 weeks from last menstrual period) the patient had spontaneous abortion (< 20 weeks) due to fetal demise. The patient did not have complication during labor/delivery. The products of conception were examined and were normal. The fetus was normal. Additional information is not expected.

Other Meds: None

Lab Data: ultrasound, 07/16/09, 11 weeks, CEDC 04-FEB-2010; beta-human chorionic, positive; serum alpha-fetoprotein, Showed increased risks of Down's

History:

Prex Illness: Pregnancy NOS (LMP = 4/16/2009)

Prex Vax Illns:

Vaers Id: **360063-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Sep-2009	24-Sep-2009	0	08-Oct-2009	09-Oct-2009	PA	WAES0909USA04823	19-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0737X		Right arm	Unknown	
MNQ	SANOFI PASTEUR	U2663AA		Left arm	Unknown	
HPV4	MERCK & CO. INC.	1486U	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB291AA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Crying, Dizziness, Dyspnoea, Dysstasia, Fatigue, Feeling abnormal, Headache, Hypoaesthesia, Hypokinesia, Injected limb mobility decreased, Injection site pain, Musculoskeletal pain, Myalgia, Nausea, Pain, Tenderness, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a physician and a licensed practical nurse concerning a 13 year old female with no pertinent medical history or no known drug allergies, who on 24-SEP-2009 was vaccinated with 0.5 ml of the first dose of GARDASIL (Lot number 659655/1486U) intramuscularly on the right arm. On the same day the patient received a dose of hepatitis A vaccine (inactive) (AVENTIS) (Lot number: AHAVB291AA) on the right arm, a dose of VARIVAX (Lot number: 661334/0737X) on the right arm, MENACTRA (Lot number U2663AA) left arm. The patient became lightheaded, had pain at the injection site, was dizzy and experienced numbness on the right leg while still in the office after vaccination. the patient was told if the symptoms got worse, to call the office or go to the emergency room (ER). The patient continued to feel bad, vomited and felt weak so the patient went to the ER. The patient was hydrated and got better. The physician reported that the patient recovered maybe on 01-OCT-2008, reported as "1 week after the first dose of GARDASIL". On 25-SEP-2009, the patient was in the office for a well visit and received the second dose of GARDASIL (Lot number 662404/0312Y) on the left arm, a dose of influenza virus vaccine (unspecified) (Lot number: U3177AA) and a dose of hepatitis A virus vaccine inactivated (Lot number 663913/0206Y) on the right arm. The patient then experienced severe pain at the injection site on the left arm. The nurse put ice on the injection site because the pain was so extreme the patient was crying. The patient was told to call the office if the symptoms got worse. The patient went to the ER. The patient had no fever. The ER notes from 27-SEP-2009, at 17:30 stated that the patient started to feel, on 25-SEP-2009, lightheaded and complained of pain all over-severe myalgia. The patient had difficulty moving her left arm and left leg. The patient got better 26-SEP-2009, but symptoms got worse 27-SEP-2009 night. The patient had nausea, dizziness sometimes, tired, aches and pains all over the b

Other Meds:

Lab Data: diagnostic laboratory, 09?/??/09, Basal metabolic normal; complete blood cell, 09?/??/09, normal Labs: CBC, BMP, UA, urine pregnancy test all normal/neg

History: None PMH: none Allergies: NKDA

Prex Illness:

Prex Vax Illns:

Vaers Id: 360064-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-May-2007	Unknown		08-Oct-2009	09-Oct-2009	PA	WAES0910USA00170	26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0244U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Autoimmune disorder, Back pain, Blindness, Depression, Eye operation, Eye pain, Fatigue, Glaucoma, Headache, Iridocyclitis, Juvenile arthritis, Ocular hyperaemia, Photosensitivity reaction, Uveitis, Vision blurred, Visual field defect, Weight increased, X-ray abnormal

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with no pertinent medical history reported and no known drug allergies who in May 2007, was vaccinated with first dose of GARDASIL (dose, route and lot number not reported). There was no concomitant medication. Sometime after receiving the first dose, the patient started complaining of joint pain of knees and back, fatigue and tiredness. Then, the patient received her second dose of GARDASIL (dose, route and lot number not reported) and in November 2007, she received her third dose of GARDASIL (dose, route and lot number not reported). A few weeks after receiving the first dose, the patient developed a full brown uveitis. The patient was given steroids (name and manufacturer unspecified) which she had a reaction to and now, the patient was legally blind, but she had some outpatient eye surgeries and developed glaucoma. The patient was taken to a Hospital to see a physician and they did blood work and X-rays of her knees and back (results not provided) and the patient was diagnosed with autoimmune disease. The patient's mother reported that the patient was put on infliximab (manufacturer unknown) and which did not help, and now was on HUMIRA which was helping her joint pain. The patient's joint pain on knees and back, fatigue and tiredness, full blown uveitis, legally blind, outpatient eye surgeries, glaucoma and autoimmune disease persisted. Follow up information was received from a registered nurse. She stated that the patient received the GARDASIL vaccinations on the following dates: the first dose was given on 03-MAY-2007 (Lot number 656051/0244U, route not reported), the second dose was given on 10-JUL-2007 (Lot number 657621/0387U, route not reported) and third dose was given on 15-NOV-2007 (Lot number 658560/1062U, route not reported). There were no concomitant vaccinations administered at the time the GARDASIL vaccinations were administered. The Registered nurse stated that there was no documentation that the patient had any

Other Meds: None

Lab Data: diagnostic laboratory 12/18/07, Lyme's disease test was negative 10/16/09 Received medical records from Ophthalmology and Rheumotology consultations from 12/18/07 to 7/13/09 Diagnostics/Labs: 12/18/07 Lyme Ab WB IgG /IgM 1.23(H), Lyme Ab E

History: None 10/16/09 Received medical records from Ophthalmology and Rheumotology consultations from 12/18/07 to 7/13/09 PMH: chronic iritis, joint pain, Lyme disease, steroid induced glaucoma. Head injury 7/19/04 hit head on road, blurry vision, HA advised ER visit.

Prex Illness:

Prex Vax Illns:

Vaers Id: **360065-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	20-May-2009		08-Oct-2009	09-Oct-2009	FR	WAES0910USA00284	09-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cell death, Cholestasis, Erythema, Face oedema, Localised oedema, Musculoskeletal pain, Oedema peripheral, Polyarteritis nodosa, Pyrexia, Skin lesion, Vasculitis

Symptom Text: Case received from the health authorities under the references numbers GR20090422 GR0901064: A 17 year old female patient received a dose of GARDASIL (lot number not reported) via intramuscular route on an unspecified date. On 12-APR-2009 the patient experienced pseudomembranous angina treated with cefixime 200 mg, DOLIPRANE, then amoxicillin and niflumic acid. On 20-MAY-2009 (reported by the health authorities as "36 days after" without further specification), the patient developed diffuse nodose and inflammatory lesions on the forearms, the external face of the right ankle and the left buttock. On 02-JUN-2009, she was hospitalized due to and oedema of the face and the neck, a periorbital erythema of "glasses" type, cutaneous lesions of the lower limbs, lesions "en cocarde" aspect, erythematous and oedematous right upper limb, diffuse arthromyalgias and fever at 39 C. Biological examinations showed polynucleosis at 34 g/L associated with normocytary anaemia at 105 g/l and an inflammatory syndrome (C- Reactive protein at 300 mg/l), cytolysis at 240 ASAT and 201 ASAT, and anicteric cholestasis (ALP at 250, GGT at 93 IU/l). Cutaneous biopsy performed on 03-JUN-2009 showed middle-sized blood vessel vascularitis, together with a necrosis of the vessel walls with fibrins deposit. Perivascular infiltrate with a predominance of neutrophil polynuclears was found, with rare eosinophils and a few lymphocytar elements. Periarteritis nodosa of musculocutaneous type was diagnosed. Differential diagnoses were as following: Infections pathologies (serologies for HIV, hepatitis B and C, Chlamydia, syphilis, brucellosis, lyme, trichinosis, cytomegalovirus, IgG positive for a former parvovirus B19, absence of IgM, bartonella and blood cultured negative). Autoimmune pathologies (antinuclear antibodies, antineutrophil cytoplasmic antibodies, rheumatoid factors negative, only C3 and C4 were increased). On 17-JUN-2009, the muscular pain had resolved. The patient progressively started walking again. Muscular pain receded under morphine

Other Meds: DOLIPRANE; Helicidine

Lab Data: Diagnostic laboratory test, ??Jun09, 34 g/L; Diagnostic laboratory test, ??Jun09, 240 ASAT and 201 ASAT; Skin biopsy, middle-sized blood vessel vascularitis, necrosis of the vessel walls with fibrins deposit; Body temp, 02Jun09, 39 C; Serum

History: Systemic juvenile chronic arthritis

Prex Illness:

Prex Vax Illns:

Vaers Id: **360066-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	08-Apr-2009	31-Jul-2009	114	08-Oct-2009	09-Oct-2009	FR	WAES0910USA00301	09-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1114U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT No reaction on previous exposure to drug, Pulmonary embolism

Symptom Text: Case received from a health care professional on 29-SEP-2009. It was reported by a gynecologist that a 21 year old female patient was vaccinated with a first dose of GARDASIL (lot number: 1114U, batch number: NH10940 on 08-APR-2009 was well tolerated (route and injection site not reported). It was reported that the patient was vaccinated with a second dose of GARDASIL (lot number: 0933U, batch number: NH40140) into the deltoid muscle on 02-JUN-2009 injection route not reported. Concomitant therapy included hormonal contraceptive VALETTE since May-2008. On 31-JUL-2009 the patient developed a pulmonary embolism and was hospitalized. At the time of the reporting the patient had not recovered. Other business partner numbers include E-2009-09036. No further information is available.

Other Meds: VALETTE

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **360072-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Feb-2009	Unknown		08-Oct-2009	09-Oct-2009	FR	WAES0910USA00303	09-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1147U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Dizziness, Heart rate irregular

Symptom Text: Information has been received from a health care professional concerning a female patient with no pertinent medical history reported who in February 2009, was vaccinated with the first dose of GARDASIL (Lot # 1147U and Batch # NH17630). Concomitant therapy was not reported. It was reported that on an unknown time post vaccination the patient experienced dizziness but she was looked after at the vaccination center. The patient did not return for her second vaccination and was then contacted by the vaccination centre who were told that the patient had been hospitalized in a children's hospital following a seizure. Whilst in hospital tests revealed an irregular heartbeat and the patient was then transferred to another hospital. The patient's outcome was not reported. Other business partner numbers include: E2009-09157. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **360075-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Aug-2009	01-Aug-2009	0	08-Oct-2009	09-Oct-2009	FR	WAES0910MYS00001	09-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Myasthenia gravis

Symptom Text: Information has been received from a consumer concerning an approximately 17 year old female who in approximately August 2009 (two months ago) was vaccinated with the second dose of GARDASIL. In approximately August 2009, a few days after receiving the second dose of the vaccine, the patient was diagnosed with myasthenia gravis. The patient's myasthenia gravis persisted. Myasthenia gravis was considered to be disabling. the administering physician did not say that the myasthenia gravis was related to the vaccine; causality is unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360085-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Oct-2009	07-Oct-2009	1	08-Oct-2009	29-Oct-2009	OR		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Pruritus, Similar reaction on previous exposure to drug, Swelling face

Symptom Text: patient noted that after 1st Gardasil in August 09 there was swelling and redness at sight of injection. After current vaccine (2nd Gardasil) there was same swelling and redness at sight but this episode also had lots of swelling and itching around anterior neck and face. Advised pt to take benadryl and not get 3rd gardasil.

Other Meds:

Lab Data:

History: mildly sensitive/allergic to certain cosmetics

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360086-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Aug-2009	15-Aug-2009	2	08-Oct-2009	22-Oct-2009	OK		12-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	06714	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Fatigue, Flushing, Myalgia

Symptom Text: Hair loss began within a few days of Gardasil. This continued at a dramatic rate so that she has lost what mom believes to be up to 50% of her hair volume. Has also had extreme fatigue and muscle soreness. 1/4/2010 PCP records for 8-11/2009, on 11/9/2009 patient with c/o's hair loss, fatigue, facial flushing

Other Meds:

Lab Data: Labs: CRP, Amylase, ESR, C3, C4, CH50, ANA, Anti-DNA, SSa, SSb, Jo1 AB all wnl/neg, TSH low, CBC wnl, UA + bacteria but urine culture negative, CMP , iron, iron sat and TIBC wnl, Antiphospholipid AB neg

History: none PMH: None Allergies: NKDA

Prex Illness: none

Prex Vax Illns:

Vaers Id: **360089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	12-Aug-2009	12-Aug-2009	0	08-Oct-2009	22-Oct-2009	CA		01-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Clumsiness, Gait disturbance, Hypoaesthesia, Immediate post-injection reaction, Inguinal hernia, Nasopharyngitis, Neck pain, Pain in extremity, Rash, Skin papilloma, Urinary tract infection

Symptom Text: Immediately: sharp pain in lower back, arm pits, and neck. Hours later: numb limbs, clumsy hands/fingers One week later: rash on the back of thighs After three weeks: rash covered most of thighs, calfs, and near under arms. Was so severe walking was painful. Visited doctor for rash at three weeks: was prescribed Pepcid AC, Benadryl, and Xyzal. I took one Pepcid and one Xyzal for 4 days and the rash went away almost completely. I stopped taking them because I got a cold. Now I use topical Benadryl for my rash, which only comes back when it is hot and humid outside. I'm only saying I didn't recover because my rash comes back every once in a while even after taking the pills. I never had a rash that painful in my life. The biggest rash I ever had before Gardasil was a couple little red bumps from grass irritation that went away in just minutes. 10/13/09 Medical Records received for Date of Service 8/12/08. Dx: UTI, Plantar wart, inguinal hernia First Gardasil shot given.

Other Meds: Necon 777 (birth control) I also take a daily Kirkland multivitamin (approved by the USP).

Lab Data: No tests were performed on me because no one believed Gardasil was to blame.

History: allergy to grass and rag weed. PMH: Allergy to Allegra on OCP's.

Prex Illness:

Prex Vax Illns:

Vaers Id: 360163-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Feb-2009	03-Mar-2009	18	09-Oct-2009	12-Oct-2009	IL	WAES0909USA01491	21-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Joint swelling, Musculoskeletal stiffness, Oedema peripheral, Pain in extremity, Rheumatoid arthritis, Tenderness

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female with hypothyroidism, eczema and acne who on 06-JUN-2008 was vaccinated with the first dose of GARDASIL (0.5ml, IM). The patient received the second dose of GARDASIL (0.5ml, IM) on unspecified date. On 13-FEB-2009 the patient received the third dose of GARDASIL (0.5ml, IM). The patient was diagnosed with viral or early rheumatoid arthritis by a rheumatologist. Her symptoms began 1 month after the third vaccination. The rheumatologist evaluated the patient in May 2009 where he said it was either viral arthritis or early rheumatoid arthritis. The rheumatologist said the patient was not in acute distress but joints were sensitive. The rheumatologist said he was leaning to early rheumatoid arthritis because of the duration of symptoms. At the reporting time the patient had not recovered. Follow-up information has been received from a clinical manager: The patient had previous drug reaction (vomiting) to codeine and CEFTIN. The patient was vaccinated with GARDASIL series as following: the first dose on 06-JUN-2008, lot# 658558/1061U; the second dose on 28-JUL-2008, lot# 658558/1061U; the third dose on 13-FEB-2009, lot# 661764/0650X; no other vaccines given on these dates. Concomitant therapy included SYNTHROID. The consult report from a rheumatologist from May 2009 showed "early rheumatoid arthritis". The report from the rheumatologist from 25-AUG-2009 showed that the patient was started on ENBREL, 50 mg weekly and methotrexate, 12.5 mg weekly for rheumatoid arthritis (RA). Follow-up information was received from the medical assistant via medical records indicating that the patient was a student and was vaccinated with three doses of GARDASIL IM in the left arm. The patient's symptoms occurred on 03-MAR-2009. On 02-MAY-2009 parvovirus B-19 antibody (IGM) was negative (<0.9), rheumatoid factor was 21 IU/ml, C-reactive protein was 0.26 mg/dl, thyroid-stimulating hormone (TSH) was 3.36 mIU/L and sed rate was 11 mm/h. She was diagnosed w

Other Meds: SYNTHROID

Lab Data: serum rheumatoid factor, 08/18/09, 347 IU/m, erythrocyte, 08/18/09, 41 mm/h; erythrocyte, 06/09/09, 17 mm/h; serum ANA, 06/09/09, negative; serum rheumatoid factor, 06/09/09. 38 IU/M; serum C-reactive, 06/09/09, 1.06 mg/d; serum cyclic citr

History: Adverse drug reaction. 10/19/09 Primary Care Records and Rheumatology consult received for dates of service 2/14/00-9/18/09. PMH: Eczema, hypothyroidism, acne, tonsillectomy, fracture of R radius, NKDA.

Prex Illness: Hypothyroidism; Eczema; Acne

Prex Vax Illns:

Vaers Id: 360168-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Apr-2007	Unknown		09-Oct-2009	12-Oct-2009	FR	WAES0910USA00287	12-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0859F	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Headache, Malaise, Nausea, Respiratory distress

Symptom Text: Case received from health authority on 28-SEP-2009 (HA reference # PEI2009020985). Case was assessed as serious, (other medical event/ probable extremely long duration of symptoms). It was reported that a 16 year old female patient was vaccinated on 30-APR-2007 with the first dose of GARDASIL (Lot # 654740/0859F, batch NE29669), the second dose of GARDASIL (lot#1341F, batch NF1376) on 25-JUN-2007, and the third dose of GARDASIL (Lot #0278U, batch NFS56940) on 16-NOV-2007, intramuscularly into the left arm. On an unspecified date, the patient developed ill feeling, headache, nausea and relapsing respiratory distress. At the time of report to health authority on 15-SEP-2009 she had not yet recovered. Medical history included DPT, HIB and poliomyelitis vaccinations (manufacturer unknown by the reporter) on 03-JUL-1991, 31-JUL-1991 and 04-SEP-1991. On 05-JAN-1991, patient experienced fever and tense fontanel, which led to hospitalization. Meningitis was ruled out. Patient received TWINRIX on 06-MAY-2002, 17-JUN-2002 and on 06-JAN-2004 (lot #HAB285A9). After the third dose the patient developed "unclear" asthenia, nausea and headache. This case was closed. Other business partner numbers included: E2009-09023. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation; Hospitalisation; Fever; Fontanelle bulging; Asthenia; Nausea; Headache

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360169-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	01-Feb-2009	01-Apr-2009	59	09-Oct-2009	12-Oct-2009	FR	WAES0910MEX00001	03-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Lupus nephritis, Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning a 27 year old female who in February 2009, was vaccinated with GARDASIL first dose, Apr, 2009 second dose. There was no concomitant medication. In April 2009, the patient experienced erythema that worsened after the second vaccine dose was received. In Aug, 2009 the patient attended to the physician's office. The physician requested laboratory tests and confirmed diagnose of erythematous systemic lupus. In Aug, 2009 the patient was evaluated by a nephrologist who diagnosed lupus nephritis. The patient's erythema, erythematous systemic lupus and lupus nephritis persisted. The reporter considered erythema, erythematous systemic lupus and lupus nephritis causality as unknown. Upon internal review lupus nephritis and erythematous systemic lupus were considered as other medical events. No further information is available.

Other Meds: None

Lab Data: diagnostic laboratory test, ??Aug?09, positive for lupus

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 360170-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Aug-2009	19-Sep-2009	24	09-Oct-2009	12-Oct-2009	AZ	WAES0909USA04824	28-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Back pain, Conversion disorder, Convulsion, Dizziness, Dyskinesia, Echocardiogram normal, Electroencephalogram normal, Muscle spasms, Muscle spasticity, Muscle twitching, Nasal congestion, Nausea, Neck pain, Nervous system disorder, Nuclear magnetic resonance imaging brain normal, Nuclear magnetic resonance imaging normal, Oropharyngeal pain, Pelvic pain, Sinusitis, Tremor

Symptom Text: Information has been received from a certified medical assistant concerning a 16 year old female patient with no pertinent medical history and no known drug reactions who on 26-JUN-2009 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot# 662404/0312Y). On 26-AUG-2009 the patient was vaccinated intramuscularly with the second 0.5ml dose of GARDASIL (lot# 662404/0312Y). There was no concomitant medication. On 19-SEP-2009 the patient developed "seizure-like activity, muscle spasms, shaking and neurological problems" after administration of GARDASIL. The patient was examined by a neurologist in the emergency room and was treated with muscle relaxers. The neurologist reported that the exam was difficult because the patient was in constant motion, flexing and extending her back. She also experiencing nausea and dizziness. The patient was not admitted to hospital. No laboratory diagnostics studies were performed. At the time of this report, the patient was recovering. Upon internal review, seizure-like activity was determined to be an other important medical event. Additional information has been requested. 10/26/09 Received medical records for DOS 9/22. DIAGNOSIS: Back spasms. Visit to ER after activity precipitated back spasms. Feeling of spasms in arms. PE neg except for erratic twitching movements. Spastic movement of torso. Strength 5+ UE/LE. No ataxia. Romberg (-). Treated in ER with Valium. SX resolved. Referred to neuro. 11/02/09 Medical records recievd for DOS 9/30-10/06. Neuro consult note: Exhibits flexion at the abdomen and umbilicus with extension and semi-fluid movements. Torso movement only. Lasts up to 24 hrs and during sleep. Back discomfort. Neuro exam WNL. Previous arm movement issue lasted 4 months and was ilicited by playing the drums. Resolved. Previous EEG WNL. Cardiac echo WNL. B/W unremarkable. Increased DNAse B antibody only. Possible conversion disorder. MRI BRain and spine WNL. Improved with tx. Referred for counseling. ```MR received 1/11/10 for 7/13/09

Other Meds: None

Lab Data: None. PMH: upper arm spasms resolved. Labs & Diags: MRI brain and spine WNL. X-rays pelvis/hips and hand neg. DNAse B Ab 120 (H).

History: None. ALLERGIES: bugs. PMH: Sexually abused by non-family member, born at 36 wks. RAD, complex febrile seizures (tonic clonic up to 20 min long), HA, dysmenorrhea, vitiligo, myringotomy tubes, ankle fx, paralabral cyst, MVA, shoulder pain.family h/o mental illnes and seizures.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360387-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Oct-2009	12-Oct-2009	0	12-Oct-2009	20-Oct-2009	PA		27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Malaise, Pallor

Symptom Text: Pt turned pale and said she felt "sick". She wanted to go get a drink I had her stay seated and she passed out. M.A. and I picked her up and laid her on the exam table. M.A. got M.D. and I stayed w/pt. We took her BP when she awoke 120/80. We let her lie for 15 min. She got up walk around and then discharged.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **360389-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-Oct-2009	13-Oct-2009	--	WAES0910USA00651	13-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse through the pregnancy registry for GARDASIL concerning a female who on unspecific date was vaccinated with a dose of GARDASIL (Lot # not provided). The nurse reported that a patient received the vaccine when she was pregnant. The patient voluntarily terminated the pregnancy when she learned that she was pregnant. Patient has sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **360390-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Feb-2009	16-Apr-2009	74	12-Oct-2009	13-Oct-2009	FR	WAES0910USA00438	13-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a Health Authority concerning a female patient born in 1989 and with a good general health status received the first dose of GARDASIL (Batch number not reported) in February 2009 and the second dose of GARDASIL (Batch number not reported) on 15-APR-2009. On 16-APR-2009, she presented with a slight facial paralysis. At the time of reporting, the outcome was unknown. To be noted that the Health Authority assessed the relationship between the vaccine and the event as unlikely. The Health Authority considered the event as medically significant. Other business partner numbers included: E2009-09190. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **360391-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Mar-2009	23-Mar-2009	0	12-Oct-2009	13-Oct-2009	FR	WAES0910USA00128	13-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Dyspnoea, Injection site erythema, Nausea, No reaction on previous exposure to drug, Pharyngeal oedema

Symptom Text: Initial case was reported on 28-SEP-2009 Health Care Professional. Additional information was received by the patient's mother the same date. It was reported that a 15 year old female with underlying asthma who on 04-FEB-2009 was vaccinated with the first dose of GARDASIL (batch# NH38510, lot# 1400U, route and site of administration not reported). On 23-MAR-2009 the patient was vaccinated with the second dose of GARDASIL (lot#, route and site of administration not reported). On 24-MAR-2009 the patient experienced an asthmatic attack. She got swollen in the throat, difficult breathing as well as dizziness. she was taken to the emergency and some tests were taken. For example blood pressure and oxygen saturation, all normal according to the mother. The patient received VENTOLINE for the asthma attack and was hospitalized for one day. The patient felt dizzy for quite a long time afterwards, but is now feeling fine. At the time of this report, the patient had recovered. The patient had underlying asthma and taken medicine (not specified) on a regular basis. But she had never experienced an asthma attack in relation to an injection before. The patient received her first dose of GARDASIL without experiencing any adverse events. Additional information was received by healthcare professional on 01-OCT-2009: The girl did not experience an asthma attack. She did in fact experience severe dizziness and nausea with onset on 24-MAR-2009. She also developed injection site redness with onset on the day of vaccination, 23-MAR-2009. On 25-MAR-2009 the patient was hospitalized over night. Blood pressure, pulse and oxygen saturation were normal. The girl was discharged from hospital the next day. Her doctor concluded that GARDASIL vaccination was the probable cause of these adverse events. The girl had a history of asthma and eating disorder. The outcome was recovered. Case is closed. Other business partner numbers included: E2009-08991. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure measurement, 25Mar09, normal; pulse oximetry, 25Mar09, normal

History:

Prex Illness: Asthma; Eating disorder

Prex Vax Illns:

Vaers Id: **360409-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Sep-2009	25-Sep-2009	0	12-Oct-2009	20-Oct-2009	OH		20-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928Y	1	Right arm	Intramuscular	FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Nausea, Photophobia

Symptom Text: Client given dose #2 GARDASIL, left treatment room, returned within 5 min. Stated began to feel nauseous, headache, dizzy almost immediately after left room. RTC BP 110/60, P 80 regular; c/o eye sensitivity to light, feeling of fatigue and headache while here. No apparent breathing difficulty. Seen by PCP-advised not to have dose #3 GARDASIL.

Other Meds:

Lab Data:

History: None

Prex Illness: Cold symptoms no fever, cough and runny nose

Prex Vax Illns:

Vaers Id: **360428-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Sep-2009	30-Sep-2009	0	12-Oct-2009	21-Oct-2009	WI		21-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0334Y	1	Right arm	Subcutaneously	
FLU	SANOFI PASTEUR	U3173DA	2	Left arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041BA		Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2876AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0702X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye swelling, Injection site erythema, Injection site pruritus, Nausea

Symptom Text: Redness and itching at site of immunization beginning within 1-2 hours and increased redness and itching at site over next 48 hours. Also had nausea and puffy eyes 24 hours after vaccine. No fever, no other rashes. History of questionable chickenpox (mild) after 1st VARRICELLA vaccine.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 360502-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Jul-2008	13-Jul-2008	10	12-Oct-2009	19-Oct-2009	--		12-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abasia, Activities of daily living impaired, Anaphylactic reaction, Anxiety, Arthralgia, Arthropod bite, Asthenia, Asthma, Bone pain, Bronchospasm, Confusional state, Conversion disorder, Convulsion, Dehydration, Depression, Diarrhoea, Disorientation, Dizziness, Drug toxicity, Dyskinesia, Dyspareunia, Dysplasia, Dyspnoea, Ear pain, Eustachian tube disorder, Eye swelling, Fall, Fatigue, Generalised oedema, Hypersensitivity, Hypertension, Hypoaesthesia, Hypoaesthesia facial, Hyporeflexia, Immediate post-injection reaction, Immune system disorder, Leukocytosis, Malaise, Movement disorder, Muscle rigidity, Musculoskeletal pain, Musculoskeletal stiffness, Myalgia, Myoclonus, Nasal congestion, Nausea, Neurological symptom, Pain, Pain in extremity, Palpitations, Paraesthesia, Paralysis, Pruritus, Rash, Rash erythematous, Rhinitis, Sensory disturbance, Sensory loss, Swelling face, Syncope, Tonsillitis, Tremor, Urinary tract infection, Urticaria, Vaginal discharge, Vomiting, Vomiting projectile, Vulvovaginal candidiasis

Symptom Text: I received the second shot of Gardasil vaccine on July 3, 2008 at 7:00 PM in my left deltoid. I immediately developed a rash following 15 minutes after vaccination. An hour after the injection, I was feeling dizzy and disoriented. I was admitted to the emergency room of the Tri-City Medical offices on July 14th, due to projectile vomit, dehydration, and weakness. I was dangerously dehydrated after throwing up more than 15 times in a single hour and was unable to swallow my own saliva without throwing up again. I was incapacitated and unable to walk, requiring to be carried into the hospital. Following my emergency room visit, I started experiencing hyper-sensitivity to my environment and products I used in my daily routine; a symptom characteristic of Polysorbate 80 poisoning considering it has been known to produce reactions of anaphylaxis, which is a constituent in the Gardasil vaccine. I experienced allergic reactions to face creams that were a customary part of my routine for years, inducing swelling of my face and nasal passages. These reactions continued without explanation and though I discontinued the use of all products that created reactions, my body's hyper-sensitivity did not dissipate. On August 2, 2008 I applied my acne cream Retin-A micro at night. By the morning, the entirety of my face had become severely swollen and did not recede completely for two days. It was so severe that it shut my right eye completely. Retin-A had never been a problem before. I was then bitten by an unknown insect in my sleep a few days later and awoke to find a swollen growth the size of a golf-ball on my arm. It was extremely itchy and an incredible ache spread through my arm and up to my shoulder. The following morning the swelling had disappeared and the ache had receded. On August 9, I started to loose all my sensation in my legs. The numbness slowly spread first throughout the left side of my body, including my face and head. In the following two days it consumed the rest of my body, numbing in

Other Meds: None

Lab Data: I'm seeking a thorough blood panel by a toxicologist, because the primary cause of my illness is based on the toxins of Gardasil. Other diagnostic tests cannot and haven't identified the cause of my symptoms, despite them being ongoing. 10

History: None 10/21/09 Medical records received for dates 6/22/08 to 10/15/09 PMH: chronic sinusitis, malaise/fatigue, anxiety disorder, asthma. Allergy to tetracycline, chloroquine, EEC, retin A, cipro, gardasil vaccine.

Prex Illness: Tonsilitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360564-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Sep-2009	03-Oct-2009	9	13-Oct-2009	22-Oct-2009	VA		27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	1	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3158AA	6	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fatigue, Hypoaesthesia, Muscular weakness, Pain in extremity, Paraesthesia, Postictal state, Tremor

Symptom Text: 10-309 Sz- 1st episode seizure - MRI negative - 10am. 10-12-09 Left hand weakness > given phenytoin - 7pm. 10/23/09 Medical records received for ER visits DOS 10/03 and 10/09. FINAL DIAGNOSES: Seizure disorder, left arm parasthesia. On 10/3 first time seizure w/prolonged postictal period. Witnessed by parents. Hard to awaken. H/O extremity shaking, numbness and tingling, dropping things w/o LOC. Usually in the am. PE wnl, (+) fatigue only. Discharged to home. Planned neuro follow-up. 10/9 patient returned to ER with c/o L hand, coldness, tingling and numbness. Subtle pain 1/3 up to elbow. Equal grasp. Developed weakness bilat legs in ER. Phenytoin tx. Resolved. Discharged to home. EEG and Neuro follow-up as planned.

Other Meds: None

Lab Data: MRI negative; EEG pending. LABS & DIAGS: chloride 108 (H), anion gap 16 (H), MRI brain- no evidence of acute infarct, non-specific white matter changes may be seen in setting of migraine HAs, gliosis, vasculitis, demyelination or Lyme's, L

History: None. PMH: Asthma. ALLERGIES: none.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360583-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Oct-2009	05-Oct-2009	3	13-Oct-2009	22-Oct-2009	OH		28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Headache

Symptom Text: Headache; Dizziness; Weakness

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360584-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Jul-2009	06-Oct-2009	67	13-Oct-2009	23-Oct-2009	FL		23-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	04708	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0216Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Rash papular

Symptom Text: Red bumps trunk, arms, legs.

Other Meds:

Lab Data:

History: Codeine Amoil,Cefzil

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360590-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	10-Sep-2009	11-Sep-2009	1	13-Oct-2009	22-Oct-2009	LA	LA100901	28-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2932AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	UF486AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0863Y	1	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Injection site erythema, Skin warm

Symptom Text: Walked in with Mom Friday am. In Raised erythema (area of varicella) did not feel good skin temp warm. Advised to go immediately to PMD.

Other Meds:

Lab Data: 9/14/2009 - Mom returned that recovered w/o difficulty. Pt was given Tylenol and Advil on a rotating schedule.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 360612-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Sep-2009	24-Sep-2009	0	13-Oct-2009	14-Oct-2009	VA	WAES0909USA04821	06-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Computerised tomogram, Concussion, Convulsion, Dizziness, Fall, Hyperhidrosis, Immediate post-injection reaction, Joint injury, Loss of consciousness, Nausea, Neck pain, Somnolence, Syncope, Tooth injury, Unresponsive to stimuli

Symptom Text: Information has been received from a physician concerning a 16 year old female with no known drug allergies, no pertinent medical history or concurrent conditions, who on 24-SEP-2009 was vaccinated with the 0.5 mL first dose of GARDASIL (lot # 663452/0671Y). No other vaccines or concomitant medications administered. The nurse administered the injection and the patient had immediate syncope with no warning and loss of consciousness for 15 seconds. The patient fell forward off the exam table, chip a tooth, scraped her knee, had a seizure and a concussion. The whole incident was 15 seconds. The physician stabilized her neck to open her airway, turned her on her back and patient came around. The patient was transported to emergency room and got a CT scan of head and neck performed (result not reported). Subsequently the patient recovered from the events. The physician's receptionist contacted during telephone follow-up, stated that the patient was not hospitalized and could not comment on disability or whether the event was life threatening, as there was no mention of this in the patient's chart. Seizure, syncope with no warning, fell forward off the exam table, chip a tooth, scraped her knee and concussion were determined to be an other important medical event by the physician. No further information is available. 12/30/09 PCP record received for DOS 09/28/07- 10/15/09. Patient had syncopal episode after receiving 1st dose of Gardasil on 09/24/09. Fell forward and hit head. Pt. was diaphoretic and unresponsive for 10-15 seconds with 3 second seizure. Transferred to ED. On 09/25/09 Pt. presents for ER followup with neck pain. Tx. with Advil. Phone call from mother on 9/28/09 reports pt. having dizziness, sleepiness and nausea. Pt. went to school on 9/29/09 with headache and persistent sensitivity to left side of face. 01/04/10 ED records received DOS 02/21/06

Other Meds: Unknown

Lab Data: Unknown

History: Unknown 12/30/09 PMH: laryngitis, cough 01/04/10 PMH: finger injury, syncope

Prex Illness: 12/30/09 laryngitis, cough

Prex Vax Illns:

Vaers Id: **360613-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-May-2009	11-May-2009	0	13-Oct-2009	14-Oct-2009	TN	WAES0910USA00171	14-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Papilloma viral infection, Rash generalised

Symptom Text: Information has been received from a registered nurse for the Pregnancy Registry for GARDASIL, concerning a 17 year old female with depressive disorder and no known drug allergies who on 17-AUG-2007 and 11-MAY-2009 was vaccinated with first dose (lot number 656051/0244U) and second dose (659184/0843X), respectively of GARDASIL. Concomitant therapy included LEXAPRO. On an unspecified date after the patient received the second dose of GARDASIL, a PAP test was positive for HPV. The registered nurse reported that the patient is now pregnant. The patient's LMP was on 01-JUN-2009 and the EDT was 08-MAR-2010. The registered nurse reported that there was an abnormality in fetus. An initial ultrasound by their office found an abnormality and the patient was referred to an unspecified perinatologist who did another ultrasound which also showed the abnormality. There were additional work ups being done followed by perinatologist and by their office. Follow up information was received from a Licensed Practical Nurse. She reported the patient was being seen for her Ob/Gyn care. The patient received 2 doses of GARDASIL at her Pediatrician's office: the first dose was administered on 17-AUG-2007 (Lot number 656051/0244U, route not reported) and the second dose was given on 11-MAY-2009 (Lot # 659184/0843X). The patient has a history of Bipolar disorder for which she was being treated with LEXAPRO (start date not reported). The patient's LMP was reported as 01-JUN-2009 and her EDD is 08-MAR-2010. The licensed practical nurse further added that the maternal great uncle of the baby's father had a history of mental retardation. The patient was on no other concomitant medications and had no other vaccinations at the same time as her GARDASIL injections. After the patient discovered she was pregnant, she stopped taking LEXAPRO (stop date not reported). The patient had a body rash during her first trimester (no further details were provided). The patient underwent a pregnancy ultrasound, the following was noted: The fetus has a misshap

Other Meds: LEXAPRO

Lab Data: Ultrasound, fetus has a misshapen skull with anterior and posterior bulging at the forehead; Pap test, Positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/1/2009); Depressive disorder; Bipolar disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360615-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Oct-2009	06-Oct-2009	0	13-Oct-2009	14-Oct-2009	FR	WAES0910COL00003	14-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Laryngeal oedema, Rash, Tongue oedema

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 06-OCT-2009 was vaccinated with GARDASIL first dose. On 06-OCT-2009 two hours after the vaccination the patient experienced skin rash, larynx edema and tongue edema, the patient was in the health center, where received basic medical care and one dose of adrenaline (dose not reported). After six hours the patient recovered from skin rash, larynx edema and tongue edema. The reporter felt that skin rash, larynx edema and tongue edema were related to therapy with GARDASIL. Upon internal review, the patient's skin rash, larynx edema, and tongue edema were considered to be other important medical events. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **360623-1 (S)** **Related reports:** 360623-2; 360623-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Oct-2009	12-Oct-2009	0	13-Oct-2009	19-Oct-2009	NJ		17-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Depressed level of consciousness, Dizziness, Fatigue, Flushing, Headache, Hypersomnia, Loss of consciousness, Pain, Unresponsive to stimuli, Vaccination complication

Symptom Text: Child became flushed about 15 minutes after administration. Progressed to dizziness and became unconscious at home. Was difficult to arouse, unknown seizure activity. Prednisione 30 mg was given, and child was taken to Emergency Room, and was evaluated. Has severe pounding headache, general body aches and very tired. Has slept excessively. 12/09/09 Immunization records received 12/10/09 MR received for DOS 10/12/09. DX: vaccine reaction to gardasil. After receiving vaccine, Pt felt flushed, lightheaded, became unresponsive for 10-15 sec, body pain. tx: orapred, motrin. Pt discharged home in stable condition.

Other Meds:

Lab Data:

History: PMH: IBS

Prex Illness: DX studies: negative for influenza

Prex Vax Illns:

Vaers Id: **360623-2** **Related reports:** 360623-1; 360623-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Oct-2009	12-Oct-2009	0	13-Oct-2009	29-Oct-2009	NJ		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Loss of consciousness, Myalgia, Somnolence

Symptom Text: Dizziness, lightheadedness, loss of conciousness, severe headache, muscleaches, excessive sleepiness

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **360623-3 (S)** **Related reports:** 360623-1; 360623-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Oct-2009	12-Oct-2009	0	22-Oct-2009	23-Oct-2009	NJ	WAES0910USA02111	17-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Influenza serology negative, Loss of consciousness, Myalgia, Orthostatic hypertension, Presyncope

Symptom Text: Information has been received from a physician and a consumer concerning her 16 year old daughter with irritable bowel syndrome, allergy to BENZYL PEROXIDE and a history of a cyst in her ovary, who on 21-APR-2009 was vaccinated with a first dose of GARDASIL. On 24-JUN-2009 the patient received a second dose of GARDASIL on 12-OCT-2009 the patient received a third dose of GARDASIL. An hour after receiving the third dose of GARDASIL the patient was found unconscious. Since she woke up from that she had experienced relentless headache, muscle pain and tiredness. The patient was admitted to the hospital on 14-OCT-2009 and kept for 24 hours. A cat scan and "blood work" laboratory studies were performed which revealed a negative result. At the time of the report the patient had improved and was able to go back to school. The patient was recovering with residual headache, residual muscle pain and residual tiredness. The patient had no problems after getting the first and second dose of GARDASIL. No further information is available. 11/12/09 Medical records and discharge summary received for 10/14/09-1 Final DX: HA, Orthstatic hypotension. Became hot and light headed. LOC. Could not talk. Flu neg. HA. Near syncope on way to have CT. D/C to home.

Other Meds: None

Lab Data: computed axial, negative; hematology, negative. Labs & Diags: Head CT WNL. HGB 11.9 (L)

History: PMH: IBS, wisdom teeth extraction. ear tubes. Allergies: benzoyle peroxide.Ovarian cyst.

Prex Illness: Irritable bowel syndrome; Hypersensitivity

Prex Vax Illns:

Vaers Id: **360659-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	12-Oct-2009	12-Oct-2009	0	13-Oct-2009	20-Oct-2009	CA		27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U3198AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	13164	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Diarrhoea, Dizziness, Headache, Nausea, Syncope, Vaccination complication, Vomiting

Symptom Text: dizziness, severe headache, nausea, vomiting 10/16/09 Medical records received for dates 10/12/09 to 10/15/09. Symptoms: Pt received vaccine 10/12/09 parent called MD office to state approx. « hour after vaccine pt. c/o dizziness, diarrhea, HA, vomiting 2-3x, syncope. F/u appt. 10/15/09 c/o stomach issues, HA, nausea. Decreased appetite continued. Assessment: Mild TTP LLQ, referred to GI specialist. Pt has HA if overeacts then vomits, stress worsens problem. DX: Possible reaction to vaccine. Chronic abdominal pain, chronic HA.

Other Meds:

Lab Data:

History: 10/16/09 Medical records received for dates 10/12/09 to 10/15/09 PMH: Abdominal pain at 3 y/o. Endoscopy at 5 y/o.(-).

Prex Illness: None known

Prex Vax Illns:

Vaers Id: 360687-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Aug-2006	10-Feb-2007	182	13-Oct-2009	20-Oct-2009	NJ		30-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	00140	3	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Disability, Emotional distress, Fatigue, Fibromyalgia, Foot deformity, Gait disturbance, Gastrooesophageal reflux disease, Goitre, Hypersomnia, Inflammation, Joint swelling, Lethargy, Limb discomfort, Malaise, Mitral valve incompetence, Mobility decreased, Muscle fatigue, Muscle spasms, Muscular weakness, Musculoskeletal stiffness, Myalgia, Neuritis, Pain, Pain in extremity, Parvovirus infection, Pulse absent, Tendonitis, Tricuspid valve incompetence, Vaccination complication

Symptom Text: I have been experiencing bilateral muscle fatigue and pain in feet and legs for almost three years now. They began when I was a 19 year old female pre-medical college student with a history of moderate alcohol use and smoking, and no major diseases except mild scoliosis as an adolescent and shingles at age 17, which indicates some auto-immune issues. I wear orthotics for my flat feet and have a history of swollen Achilles tendons and other feet problems. I was in great physical shape as I exercised five times a week for an hour. After volunteering in a hospital, on my feet for three hours, I experienced a sudden onset of intense foot pain in February 2007 which disabled my mobility for the rest of the day. From then on, my leg muscles were extremely weak and fatigued so much that I was not able to climb up stairs or walk from my dorm to classes on campus. I also experience sporadic pain throughout different places in my legs and feet, including knee, ankle, thigh, and foot pain. Sometimes the pain is so bad I will all of a sudden be forced to limp as I cannot put any pressure on my foot after it has a sort of spasm. I sometimes experience these spasms while driving and have to pull over and can no longer drive, and I can no longer drive longer distances. I also experience stiffness and aches in my legs and feet late in the night, in the mornings, and after keeping them in one position for awhile. After I drink alcohol, my symptoms become worse and more frequent for the following week proportionate to the amount of alcohol consumed. Podiatrist Evaluation Feb. 2007: Podiatrist examined my orthotics which were too old and diagnosed me with congenial pes planus and limb pain. Podiatrist took a slipper cast of each foot and made orthotics which corrected the pes planus as best as they could. Podiatrist ordered physical therapy three times a week to strengthen my leg muscles which were extremely weak during strength and resistance testing. Podiatrist referred to a back specialist to determine if any lower back proble

Other Meds: Yasmin

Lab Data: - Back specialist took X-Ray of lower back to determine if any lower back problems at the Center are influencing the leg issues in March 2007. X-Ray was normal. - Orthopedist then ordered a nerve conduction test and electromyography (EMG)

History: Allergic to ceclor ```1/11/2010 Orthopedic records from 3/2007-8/2009, Dx pes planus deformity, forefoot varus deformity, posterior tibial tendinitis PMH: Shingles and Scoliosis Allergies: PCN and Ceclor

Prex Illness: No ```1/11/2010 Orthopedic records from 3/2007-8/2009, Dx pes planus deformity, forefoot varus deformity, posterior tibial tend

Prex Vax Illns:

Vaers Id: **360711-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Oct-2009	07-Oct-2009	0	13-Oct-2009	22-Oct-2009	MT		22-Oct-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0850Y	1	Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB360BA	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0570X	1	Left arm	Intramuscular	
FLU	CSL LIMITED	02149211A	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ear pain, Eye movement disorder, Syncope

Symptom Text: Upon injection pt momentarily fainted: Eyes closed, body slumped. Eye lids fluttered open & pt began to cry saying her "ears hurt". Laid pt. down - applied cool paper towels to forehead. Pt rested & felt better after Approx 15 min.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **360753-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Nov-2008	01-Dec-2008	30	14-Oct-2009	19-Oct-2009	IA		03-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570	0	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Addisons disease, Arthralgia, Fatigue, Myalgia, Weight decreased

Symptom Text: 2 wks post vaccine -> myalgia/fatigue. Wt loss. Ultimate diagnosis Addison's Disease 8/09. 10/26/2009 PCP and Endocrinologist records, initial visit 8/13/2009. Patient with c/o's fatigue, arthralgias, myalgias and an 18 lb unexplained wt loss. Baseline cortisol levels were <1, patient dx'd with Addison's disease. Tx: started on hydrocortisone bid.

Other Meds:

Lab Data: Cortrosyn stim was flat Labs: CBC, CRP, ANA, VIT D, Rennin, Blood Mercury normal, BMP : Na low, ACTH, Varicella AB test neg, Lyme test neg Dx studies: MRI Brain wnl

History: None PMH: none Allergies: NKDA

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360765-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-Sep-2009	15-Sep-2009	0	14-Oct-2009	26-Oct-2009	OH		05-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain

Symptom Text: Persisted pain in deltoid area (site of injection) with limited ROM due to pain but no redness or swelling 1 month after injection.

Other Meds: ranitidine; ORTHO-TRICYCLEN LO

Lab Data:

History: GERD; Migraine; Acne; Atopic Dermatitis; Allergic Rhinitis

Prex Illness: none known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360767-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	24-Sep-2009	24-Sep-2009	0	14-Oct-2009	26-Oct-2009	MT		26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain

Symptom Text: Vaccine received 9/21/09 without incident. Today (9/24/09) sudden onset pain and numbness- mostly resolved x 1 hour later.

Other Meds:

Lab Data:

History:

Prex Illness: none known

Prex Vax Illns:

Vaers Id: 360772-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Sep-2009	30-Sep-2009	0	14-Oct-2009	26-Oct-2009	--		10-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dermatitis contact, Eye pruritus, Eye swelling, Oral pruritus, Pruritus, Rash, Swelling face

Symptom Text: My 12 year old daughter received her second GARDASIL shot Wednesday, September 30, 2009. She complained of her tongue itching later that night. I started giving her ZYRTEC. The next day she was complaining of itching her face around her eye. I gave her ZYRTEC twice a day until Friday night when she developed a rash on the right side of her face around her eye. At that point I started giving her BENADRYL every four hours. Her face was significantly swollen on the right side by Saturday night. Sunday morning, her eye was swollen nearly shut. The right side of her face was swollen so severely, she was unrecognizable from her profile. I applied cool compresses, continued BENADRYL, and gave TYLENOL for the discomfort. I tried to get an after hours appointment but was told by th on-call nurse to continue the BENADRYL and that unless she had blister, there was no reason to see the doctor. Monday her eyes were completely swollen shut, and her skin was so lightly swollen the itching had subsided. I did get her a doctor's appointment that afternoon but was told it was contact dermatitis, and that it had nothing to do with the second GARDASIL shot that she had five days earlier. I asked the doctor to document the possibility that it was a reaction to the shot in her records. She said it was worth noting but that she had not seen any such reactions. I do not believe she documented it. She prescribed 60mg of PREDNISONE a day for five days and told me to continue to giver her the 50 mg of BENADRYL every four hours. By Monday night the very raw and irritable rash had spread to the other side of her face. Tuesday the swelling on the right side had lessened but her cheek and eye were still puffy and the hives were still very raw. Tuesday night the rash had spread to cover most of the left side of her face, behind both ears toward the back of her neck, and under her chin, down her neck and onto her chest. I continued to following doctor's instructions giving her the BENADRYL and PREDNISONE. Wednesday morning the redness had subsi

Other Meds:

Lab Data:

History: She does have eczema.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360773-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Oct-2009	07-Oct-2009	0	14-Oct-2009	26-Oct-2009	MI		26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3030AA	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3196AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Pt developed gen rash approx 15 min following imm. 50 mg BENAFRYL PO given. Denied itching, diff breathing, throat swelling. Mother states same gen rash reaction following 1st GARDASIL imm. resolved with time and BENADRYL per mother.

Other Meds:

Lab Data:

History: Asthma; ADHD

Prex Illness: none

Prex Vax Illns:

Vaers Id: **360791-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	02-Oct-2009	04-Oct-2009	2	14-Oct-2009	26-Oct-2009	IN		26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives. Advised to take BENADRYL. Prednisone.

Other Meds: None

Lab Data:

History: Acne; ADD; mild thyromegahy

Prex Illness: None

Prex Vax Illns:

Vaers Id: **360833-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Jul-2009	22-Jul-2009	0	14-Oct-2009	15-Oct-2009	--	WAES0910USA00802	26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Latent tuberculosis, Vaginal haemorrhage

Symptom Text: Information has been received from a medical assistant and a nurse, for the Pregnancy Registry for GARDASIL, concerning a 16 year old female patient who on 22-JUL-2009 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (reporter not able to locate lot number). The patient was a "refugee" and came to the new country on 11-JUN-2009. On 16-SEP-2009, the patient was seen in Health Department had a Pregnancy test which was positive. The patient Last Menstrual Period was 07-JUL-2009. On 28-SEP-2009, the patient was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL (lot # 662518/0087Y) and concomitantly received FLUZONE (lot# U3174EA), the third dose of RECOMBIVAX HB (lot # 663313/1445X), the second dose of VAQTA (lot # 664625/0810Y) and IPOL (lot # B0476). On 28-SEP-2009, the patient was seen for latent tuberculosis and was prescribed isoniazid therapy. On 03-OCT-2009, the patient had a miscarriage and was seen in hospital. The patient was only 6 weeks pregnant at the time of miscarriage and reason for miscarriage unknown. The patient was not admitted to the hospital. On 06-OCT-2009, the patient was seen in a Pediatric Clinic and had menstrual type bleeding at that time. On 08-OCT-2009, the patient was schedule for follow-up laboratory blood tests and was to be referred to Family Planning. At the time of the report, the patient was recovering. Upon internal review, miscarry was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic, 09/16/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = 7/7/2009)

Prex Vax Illns:

Vaers Id: **360836-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-Sep-2009	29-Sep-2009	0	14-Oct-2009	15-Oct-2009	FR	WAES0910USA00929	15-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK19200		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Fall, Haematoma, Syncope

Symptom Text: Information has been received from a health authority concerning an 11 year old female who was vaccinated on 29-SEP-2009 with one dose of GARDASIL (batch number NK19200). On the same day, after vaccination, she presented with a lipothymic crisis and a large hematoma due to falling. She was admitted to the hospital for the further investigations (NOS). The outcome was not reported. The case is closed. Other business partner number include E2009-09260.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360860-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Sep-2009	05-Oct-2009	12	14-Oct-2009	26-Oct-2009	GA		27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	U522U	1	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB343BA	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised, Skin papilloma

Symptom Text: Rash with wart like lesions on entire body.

Other Meds:

Lab Data: Referred to dermatologist.

History: Drug allergy to PCN and Sulfa.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **360862-1** **Related reports:** 360862-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Oct-2009	14-Oct-2009	0	14-Oct-2009	26-Oct-2009	OH		04-Jan-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3029AA	0	Left arm	Unknown	FLUN
HPV4	MERCK & CO. INC.	0249Y	0	Right arm	Unknown	
VARCEL	MERCK & CO. INC.	0928Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Headache, Neurological examination normal, Syncope, Tonic clonic movements

Symptom Text: She received GARDASIL # 1, fainted and had sm seizure last about 8 sec. 1030 = Mom called back and stated she had severe Ha (History migraines. 11/24/09 and 11/25/09 MR and Vaccine record received for DOS 10/14/09 S/P vaccine, Pt experienced fainting, seizure for 18 sec and severe headache. Pt recovered. 12/01/09 Medical records received for DOS 10/07/09 - 10/14/09. Syncope after vaccine. Very brief tonic clonic movements. Upon PE alert, neuro exam neg.

Other Meds: None

Lab Data: None

History: 11/24/09 MR for DOS 10/14/09: PMH: hx of migraines

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360862-2** **Related reports:** 360862-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Oct-2009	14-Oct-2009	0	02-Nov-2009	03-Nov-2009	OH	WAES0910USA03538	11-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Headache, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a physician concerning a female patient who fainting and possible seizure. The patient recovered on an unspecified date. The patient sought unspecified medical attention. Upon internal review seizure was considered to be an other important medical event. Additional information has been requested. 11/24/09 and 11/25/09 MR and Vaccine record received for DOS 10/14/09 S/P vaccine, Pt experienced fainting, seizure for 8 sec and severe headache. Pt recovered. 11/24/09 MR for DOS 10/14/09: 12/01/09: VAERS report received. 12/01/09 Medical records received for DOS 10/07/09 - 10/14/09. Syncope after vaccine. Very brief tonic clonic movements. Upon PE alert, neuro exam neg.

Other Meds: Unknown

Lab Data: Unknown

History: PMH: hx of migraines

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **360865-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	02-Jun-2009	02-Jun-2009	0	14-Oct-2009	29-Oct-2009	MO		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect product storage

Symptom Text: GARDASIL vaccine was noted at temperature that was out of normal range.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **360892-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Sep-2009	04-Oct-2009	10	14-Oct-2009	26-Oct-2009	FL		26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Hair is falling out in greater amount than normal.

Other Meds:

Lab Data:

History: none

Prex Illness: No illness; was at doctor's office for school sport physical exam and decided to start Gardisil vaccine with first shot.

Prex Vax Illns:

Vaers Id: **360943-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Oct-2009	10-Oct-2009	0	15-Oct-2009	29-Oct-2009	VA		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2928AA	0	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	C3098A	0	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334BA	0	Unknown	Intramuscular	
	FLU	SANOFI PASTEUR	U3185AA	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Hypotonia, Immediate post-injection reaction, Musculoskeletal stiffness, Syncope

Symptom Text: Immediately after administration all the above vaccine she became limp then stiff - eyes rolled up - fainted - helped to the floor within a minute she recovered fully - vitals signs normal. No treatment given - paramedics came - no medications given - stable.

Other Meds: Uses Albuterol HFA

Lab Data: None

History: Asthma; Allergic rhinitis : Dermatitis; Suicide attempt

Prex Illness: Follow-up for asthma

Prex Vax Illns:

Vaers Id: **360944-1** **Related reports:** 360944-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Nov-2008	Unknown		15-Oct-2009	16-Oct-2009	--	WAES0908USA04293	16-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	2	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2760AA	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Autoimmune thyroiditis, Fatigue, Hypothyroidism, Menstruation irregular, Myalgia

Symptom Text: Information has been received from a physician concerning a 13 year old female who in 2008 was vaccinated with GARDASIL. The patient completed the series of GARDASIL in 2008 and was recently diagnosed with Autoimmune Thyroiditis (2009). The patient sought her pediatrician. At the time of the reporting, the patient had not recovered from the event. Follow up information received on 06-OCT-2009 from a physician via medical records indicated that the patient was female student, with no medical history, known allergies or illness at the time of vaccination. The patient's family history included hypothyroidism and polycystic ovary syndrome (mother), aniridia (brother) and hypothyroidism (paternal grandmother). On 26-NOV-2008 the patient was vaccinated with a third dose of GARDASIL (lot # 650557/0072X), intramuscularly into the left arm. Secondary suspect vaccination given on the same day included a third dose of FLUZONE, (lot # U2760AA), intramuscularly into the right arm. The patient presented with her mother in the physician's office on 19-MAY-2009, complaining of feeling tired, muscle aches and requiring long naps. She has been experiencing these symptoms for the last couple of months (end of school year). The myalgias were generalized and most pronounced in her knees, hips and shoulders. TYLENOL helps some. She has been sleeping well-getting 8 hours of sleep without significant interruption. She generally feels well rested in the morning. She has not been short of breath and she denies fever, chills, night sweats, nausea, vomiting. She started her menstrual periods last July and they have been irregular. Her mother noticed that the fatigue and body aches were more pronounced just prior to her most recent menstruation. She had no urinary problems and she denied increase thirst. She grew approximately 2 inches in height in the past year. The physical exam was within normal limits. The patient developed hypothyroidism diagnosed on 19-MAY-2009 with symptoms beginning in March 2009 (approximate). The patient had a comp

Other Meds: Unknown

Lab Data: blood pressure, 114/5; serum TSH, 05/19/09, 12.06 UIU/, high; neutrophil count, 05/19/09, 53 %, lymphocyte count, 05/19/09, 36 %; monocyte count, 10 %; temperature measurement, 36.2 degrees C; respiratory rate, 18; total heartbeat count, 52

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **360944-2** **Related reports:** 360944-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Nov-2008	Unknown		27-Oct-2009	28-Oct-2009	--	200904410	14-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2760AA	2	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Autoimmune thyroiditis, Fatigue, Hypersomnia, Hypothyroidism, Menstruation irregular, Myalgia, Pain

Symptom Text: Information received on 20 October 2009 from another manufacturer (report number WAES 0908USA04293) whose initial reporter was a physician. "Information has been received from a physician concerning a 13 year old female who in 2008 was vaccinated with GARDASIL. The patient completed the series of GARDASIL in 2008 and was recently diagnosed with Autoimmune Thyroiditis (2009). The patient sought her pediatrician. At the time of the reporting, the patient had not recovered from the event. Follow up information received on 06-OCT-2009 from a physician via medical records indicated that the patient was female student, with no medical history, known allergies or illness at the time of vaccination. The patient's family history included hypothyroidism and polycystic ovary syndrome (mother), aniridia (brother), and hypothyroidism (paternal grandmother). On 26-NOV-2008 the patient was vaccinated with a third dose of GARDASIL (lot # 660557/0072X), intramuscularly into the left arm. Secondary suspect vaccination given on the same day included a third dose of FLUZONE, (lot # U2760AA), intramuscularly into the right arm. The patient presented with her mother in the physician's office on 19-MAY-2009, complaining of feeling tired, muscle aches and requiring long naps. She has been experiencing these symptoms for the last couple of months (end of school year). The myalgias were generalized and most pronounced in her knees, hips, and shoulders. TYLENOL helps some. She has been sleeping well-getting 8 hours of sleep without significant interruption. She generally feels well rested in the morning. She has not been short of breath and she denies fever, chills, night sweats, nausea, vomiting. She started her menstrual periods last July and they have been irregular. Her mother noticed that the fatigue and body aches were more pronounced just prior to her most recent menstruation, She had no urinary problems and she denied increase thirst. She grew approximately 2 inches in height in the past year. The physician exam was within normal l

Other Meds:

Lab Data: The following labs were done on 19 May 2009: bp 114/58; basophil 0%; esoinophil 1%; lymphocyte 36%; monocyte 10%; neutrophil 53%; serum TSH 12.060; anion gap 20; hr 52; temperature 36.2; respirations 18.

History: not reported

Prex Illness:

Prex Vax Illns:

Vaers Id: 360945-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Oct-2009	08-Oct-2009	0	15-Oct-2009	16-Oct-2009	AL	WAES0910USA00980	16-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	500711P		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0216Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Head injury, Loss of consciousness, Musculoskeletal stiffness

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female who on 08-OCT-2009 was vaccinated with her second 0.5mL dose of GARDASIL (route and lot number not reported). Concomitant therapy included FLUMIST. IT was reported that half an hour later, on 08-OCT-2009, the patient experienced passed out, hit her head and had a seizure. The patient was taken to the emergency room and was released. The physician felt it was important to note that the patient had not eaten prior to vaccination. The patient recovered from hit her head, passed out and seizure on the same day. Follow up information was received from a registered nurse concerning the 14 year old female patient with no pertinent medical history reported and no known drug allergies who on 08-OCT-2009 was vaccinated with her second dose of GARDASIL (lot number 663451/0216Y) and concomitantly with a dose of FLUMIST (lot number 500711P). The registered nurse reported that the patient left the office and was in a restaurant when she "passed out and stiffened" on 08-OCT-2009. The patient was taken to the ER where a CT of the head, EKG, chest X-ray and blood work were performed (all normal). No treatment was needed. It was noted that the patient received the first dose of GARDASIL (route not reported, lot number 664780/0904Y, valid for ROTATEQ) on 16-JUL-2009. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: electrocardiogram, 10/08/09, Normal; chest X-ray, 10/08/09, Normal; head computed axial, 10/08/09, Normal; diagnostic laboratory, 10/08/09, Blood work: Normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **360946-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Dec-2008	01-Jan-2009	31	15-Oct-2009	16-Oct-2009	FR	WAES0910USA01110	02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Anxiety, Arthralgia, Asthenia, Convulsion, Dizziness, Influenza, Monoplegia, Myalgia, Pain in extremity, Paralysis, Vaccine positive rechallenge

Symptom Text: Information has been received on 06-OCT-2009 by Health Authority (HA ref. DK-DKMA-20092549) concerning a 15 year old female who in ultimo December 2008, was vaccinated with the first dose of GARDASIL intramuscularly (lot#, batch# and site of administration not reported). There was no concomitant medication. It was reported that on 01-JAN-2009 the patient experienced muscular pain, convulsions, joint pain, dizziness and weakness. The patient was diagnosed with influenza by the doctor from the emergency service and received treatment with PANODIL (manufactured by GlaxoSmithKline, dose not reported, no dates reported). According to the patient's parents, the symptoms were not consistent with influenza, thus the patient's GP was contacted a few days later. The patient was referred for a neurological examination that revealed no abnormalities except paralysis of extremities. It was not specified which examinations that were performed or the date of neurological examination. One week later, the patient's condition had not improved. The patient was seen by a reflexologist who stated that the patient was "cold" (not further specified). The patient was treated with warmth, reflexology and diet advice (not further specified). It was reported that patient's condition improved slowly and the patient recovered on an unspecified date. It was reported that the symptoms returned in February 2009 (not further specified), and that the patient also experienced anxiety due to the uncertainty regarding causality. The neurological examination was repeated with the same conclusion (no abnormalities except paralysis of extremities). After a week, the symptoms had declined and the patient recovered. In primo March 2009, the patient was vaccinated with the second dose of GARDASIL intramuscularly (lot#, batch# and site of administration not reported). No adverse reactions were reported. In primo May 2009, the patient was vaccinated with the third dose of GARDASIL intramuscularly (lot#, batch# and site of administration not reported). It wa

Other Meds: None

Lab Data: neurological examination, paralysis of extremities

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Oct-2009	15-Oct-2009	0	15-Oct-2009	16-Oct-2009	PA		16-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045CA	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3210AA	0	Right arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	500756P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0819Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus

Symptom Text: Child c/o itchiness of b/l arms. No rash present. Child was otherwise well. VSS. Lungs CTA. MD was notified. Benadryl given. CHild stayed in office x 30 min. Itching resolved. No further intervention required.

Other Meds: None

Lab Data: n/a

History: Hx of headaches and anemia

Prex Illness: n/a

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361035-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	19-Oct-2007	10-Oct-2008	357	15-Oct-2009	22-Oct-2009	NY		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: 2 swollen lymphnodes on left neck and 1 on right neck. After blood work December and again in May (with a chest X-ray), results came back inconclusive and was concluded to be a result of vaccination. LAD still present today. Lymph nodes seemingly more reactive to illness than ever before. 10/26/2009 records from multiple MD visits. Patient with c/o's swollen cervical lymph nodes, noted since 9/2008. PE: noted multiple rt and lt sided subcentimeter nodules that were mobile and non-tender. No tx noted, patient to return if any enlargement or change in nodules is noted.

Other Meds: Nuva Ring

Lab Data: Blood work Chest X-ray negative for LAD in chest. Labs: Cbc, rbc and mchc low. Thyroxine 13.3 high, Bmp wnl, Esr normal at 11, cat scratch, monotest neg Dx tests: Cxr wnl Received follow up doses in January and August 2008 (approximate

History: No PMH: none Allergies: NKDA

Prex Illness: No

Prex Vax Illns:

Vaers Id: 361047-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Sep-2009	28-Sep-2009	0	15-Oct-2009	26-Oct-2009	CA		26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2846AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1749X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised

Symptom Text: The patient developed severe itching that began on the trunk and spread to entire body. No obvious rash. Treated with benadryl 50 mg IM. Itching abated.

Other Meds: Singulair, patanase

Lab Data: None

History: Enviornmental allergies.

Prex Illness: NO

Prex Vax Illns:

Vaers Id: 361071-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Oct-2004	06-Oct-2009	1826	15-Oct-2009	29-Oct-2009	TX		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Hyperhidrosis, Loss of consciousness, Nausea, Pulse abnormal, Skin discolouration, Syncope

Symptom Text: HPV vaccine admin deltoid. 1 minute or less later, pt had syncopal episode and quickly revived with ammonia capsule. 2 min later/LOC; BP not audible, pulse thready, diapharetic, gray color - IV started with normal saline O2 per mask, EMS called - revived - NO ER visit. Nausea and headache remainder of day.

Other Meds: Minocycline

Lab Data: EKG; CBC; CMP; - all normal results

History: Childhood - exercise included asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361110-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Oct-2009	19-Oct-2009	NY	WAES0910USA01368	19-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervix carcinoma

Symptom Text: Information has been received from a woman concerning her daughter who was vaccinated with a dose of GARDASIL on an unspecified date. Subsequently the patient was diagnosed with cervical cancer. The reporter said it was because of the vaccine. The reporter mentioned that a doctor was running a series of tests on her daughter to find out exactly what it was or what might be the cause. At the time of the report, the outcome was unknown. Upon internal review, cervical cancer was considered to be an other important medical event. Attempts are being made to verify the existence of an identifiable patient.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 361111-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Apr-2009	22-Sep-2009	171	16-Oct-2009	19-Oct-2009	CA	WAES0910USA01162	13-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Abdominal pain, Abdominal pain upper, Asthenia, Back pain, Conversion disorder, Diabetes mellitus, Headache, Hiatus hernia, Migraine, Musculoskeletal pain, Obesity, Paraesthesia, Reflex test normal, Rehabilitation therapy, Walking aid user, Walking disability

Symptom Text: Initial and follow-up information has been received from a physician concerning a 14 year old female with unspecified mental health issues who on 04-APR-2009 was vaccinated with a dose of GARDASIL (dose, route and LOT# not reported). On 22-SEP-2009 the patient started complaining of abdominal pain and weakness. The patient was admitted to hospital and felt fine when she discharged on 25-SEP-2009. On 27-SEP-2009 the patient went to emergency room and was admitted again for headache, weakness and being unable to walk. The labs CT of head and CT of spine were performed and no outcome provided, the GUILLAIN-BARRE Syndrome test was negative. The patient had been discharged on an unspecified date but she was still unable to walk and had weakness. No further information was available at this time of the report. The patient was hospitalized. The reporter considered the abdominal pain, weakness, headache and being unable to walk to be an incapacity or significant disability. Additional information has been requested. 11/9/09 medical records and discharge summary received for DOS 9/22-9/25 and subsequent admission 10/27/09-10/02/09. Final DX: 9/22 admission- Hiatal hernia. FInak DX 10/27 admission - Migraine Headaches, Somataform Disorder, Diabetes, Obesity Patient initially admitted for stabbing epigastric/abd pain and pain in shuoulders and back, tingling in back. CT abd and pelvis neg. diagnosed w/small hiatal hernia by endoscopy. D/C to home. Returned to ED with c/o LE weakness and back pain. Also c/o severe HA. Unable to bear weight and walks with walker. DTRs 1/4. Normal sensation. Strength 5/5. All diags neg. Somataform disorder. Refer to psych and possible rehab/PT. Homehealth. D/C using walker. HA resolving.

Other Meds: Unknown

Lab Data: diagnostic laboratory, negative for GUILLAIN-BARRE Syndrome LABS & DIAGS: Glucose 114, CRP 2.6 (H), acetylcholine binding neg. CSF cx w/gram stain no growth. ABD U/S liver diffuse fatty infiltration mild hydronephrosis R side. EGD- mild

History: PMH: Obesity. DM (well controlled on PO meds). Family h/o asthma , DM and hypertension. ALlergies: NKDA

Prex Illness: Mental disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361112-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	01-Feb-2009	10-Mar-2009	37	16-Oct-2009	19-Oct-2009	FR	WAES0910CZE00001	03-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Hypoaesthesia, Multiple sclerosis, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 27 year old female with multiple sclerosis (1st attack in summer 2008 - paresthesia of left lower extremity). This woman was in middle of February 2009 vaccinated with GARDASIL, 1st dose. During vaccination patient was without problems and she was not on any therapy. On 10-MAR-2009 the patient experienced hypoaesthesia and paresthesia generalised, and from March 13 to March 19, 2009 she was hospitalized. During hospitalization were done following tests: magnetic resonance imaging - Thorax spine - finding: nidus 7.5 x 2.5 mm in C3 location; magnetic resonance imaging - Brain - finding: few supratentorial plaques; lumbar punction - findings: leucocytes - 14; plasmatic cells presented in cytology exam; cerebrospinal fluid oligoclonal band profile test (results not reported). The reporter conclude that this is 2nd attack of multiple sclerosis. The reporter felt that hypoaesthesia and paresthesia generalised (multiple sclerosis, worsening) could be related to vaccination with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, ??Mar09, Thorax spine - nidus 7.5 x 2.5 mm in C3 location; magnetic resonance imaging, ??Mar09, Brain - few supratentorial plaques; spinal tap, ??Mar09, leucocytes -14; in cytology plasmatic cells presented; CSF

History:

Prex Illness: Multiple sclerosis

Prex Vax Illns:

Vaers Id: 361113-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Aug-2009	12-Aug-2009	7	16-Oct-2009	19-Oct-2009	PA	WAES0910USA01313	11-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Balance disorder, Condition aggravated, Conjunctivitis, Fatigue, Gastritis, Headache, Impaired work ability, Muscle spasms, Muscle twitching, Nausea, Photophobia, Tremor, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 19 year old female patient with headaches (one every couple of months) and a history of aspirin causing a rash and a bee sting causing a local reaction who was vaccinated intramuscular (right arm) with 0.5 ml dose of GARDASIL on 05-AUG-2009 (Lot # 659054/0315Y) and on 30-SEP-2009 (Lot # 662304/1013Y) respectively. The physician reported an increase in headaches after administration of GARDASIL. The reporter mentioned that a week after receiving her first dose of GARDASIL "approximately on 12-AUG-2009" the patient started experiencing headaches 2 to 3 times a week. It was reported that five days after her second dose "on 05-OCT-2009" the patient started to experience disabling headaches 2 to 3 times a day, severe involuntary muscle spasms in her right arm, tremors, nausea and weakness. Also was reported that the patient was so weak that she was not able to work. The patient was examined in two emergency rooms on 07-OCT-2009 and on 11-OCT-2009 respectively but the patient was not admitted to the hospital either time. The reporter mentioned that she was treated with IMITREX, BENADRYL, "pain medicine", and ondanstron. The patient will have an appointment with a Neurologist (name not provided) on 15-OCT-2009. It was reported on 14-AUG-2009 as laboratory and diagnostics test a CAT (Computed Axial tomography) scan and MRI (Magnetic resonance Imaging) of brain: normal; Blood chem., CBC (Complete Blood Cell Count) and urinalysis: all negative and a PAP (Papanicolaou test) smear without results. The patient sought medical attention in office visit. at the time of reporting the patient was not recovered. Additional information has been requested. 01/04/, 01/06 & 01/07/10: ED Record and Primary Careand Vaccine Records received for dates of service 8/5/09 to 10/22/09. Headaches, fatigue, gastritis, tremors, conjunctivitis Presented to ED with c/o HA's x 1 year with nausea and photophobia, sometimes with twitching in RUE. Started on Topamax. Also seen for

Other Meds: hormonal contraceptives

Lab Data: computed axial, 08/14/09, Normal; magnetic resonance, 08/14/09, Normal; diagnostic urinalysis, 08/14/09, Negative; hematology, 08/14/09, Negative; complete blood cell, 08/14/09, Negative.01/04/, 01/06 & 01/07/10: ED Record and Primary Care

History: Bee sting; Local reaction; Rash. 01/04/, 01/06 & 01/07/10: ED Record and Primary Careand Vaccine Records received for dates of service 8/5/09 to 10/22/09. PMH: Bronchitis and Pneumonia, IBS, Allergy to aspirin.

Prex Illness: Drug hypersensitivity; Headache

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361121-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Oct-2009	19-Oct-2009	FR	WAES0910USA00977	19-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a nurse practitioners' patient who heard on radio that "HPV vaccine killed someone in the country". The cause of death was unknown. The reporter was not sure if the vaccine was GARDASIL or CERVARIX. Attempts are being made to verify the existence of an identifiable patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 361126-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-Aug-2008	01-Dec-2008	104	16-Oct-2009	19-Oct-2009	FR	WAES0910USA01434	02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ecchymosis, Haematoma, Petechiae, Systemic lupus erythematosus, Thrombocytopenia, Thrombocytopenic purpura, Vaccine positive rechallenge

Symptom Text: Information has been received from Health Authorities (reference numbers BR20090281 NS/29/CHU/ICH) concerning a 20 year old female patient who on 29-FEB-2008 was vaccinated intramuscularly with the first dose of GARDASIL (batch number NH00400, lot number 1146U). On 26-APR-2008 the patient was vaccinated intramuscularly with the second dose of GARDASIL (batch number NH00400, lot number 1146U). On 19-AUG-2009 the patient vaccinated intramuscularly with the third dose of GARDASIL (batch number NH13370, lot number 1208U). The patient was concomitantly taking contraception. In December 2008, during a blood donation, a thrombocytopenia at 90 giga/l platelets was discovered. The patient then mentioned that during the vaccination, she had experienced petechias with hematomas. When she consulted in September 2009, she did not present with hemorrhagic symptomatology. However, she easily presented with ecchymosis. Blood cells count found a thrombocytopenia at 69 giga/l with an index of immature platelets at 20%. No impairment of other blood lineages was found. There was no coagulation activation (D-dimer inferior to 0.20 mcg/ml), no circulating anticoagulant nor antithromboplastin. Antinuclear antibodies very positive were found of specked type. Native anti-DNA antibodies were positive. HIV hepatitis B and C serologies were negative. The Health Authorities concluded to an isolated thrombocytopenia, probablement peripheral, in the context of a lupus with positive antinuclear antibodies and positive anti-DNA antibodies. The thrombocytopenia appeared a few months after the three injections vaccine. Laboratory results were as following: September 2009: Fibrinogen at 3.63 gl, White cells at 3.4 giga/l, Hemoglobin 12.8g/dL; Prothrombin time at 92%; Mean corpuscular volume at 83fL; December 2007: platelets at 278 giga/l; December 2008: platelets at 90 giga/l. At the time of reporting, the outcome was unknown. Lupus erythematosus, thrombocytopenia, and purpura thrombocytopenic were considered to be other important medical events. T

Other Meds: Hormonal contraceptives (unspecified)

Lab Data: platelet count, ??Dec07, 278 giga/l; platelet count, ??Dec08, 90 giga/l; WBC count, ??Sep09, 3.4 giga/l; hemoglobin, ??Sep09, 12.8 g/dL; plasma fibrinogen test, ??Sep09, 3.63 g/l; prothrombin time, ??Sep09, 92%; mean corpuscular volume, ??S

History:

Prex Illness: Contraception

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361130-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Oct-2009	13-Oct-2009	0	16-Oct-2009	29-Oct-2009	KY		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3067AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle spasms, Pain in extremity, Pyrexia, Vomiting

Symptom Text: Shortly after giving shots to the patient, the patient started having pain in right arm, and having muscle spasms. Pain continued along with a fever reaching 102.3. This was within 2 to 3 hours after injection. On 10-14-09 patient started vomiting. On 10-15-09 talked to mom and she said she is doing much better.

Other Meds: TOPAMAX; DEPAKOTE.

Lab Data: None

History: Migraines.

Prex Illness: Having back pain.

Prex Vax Illns:

Vaers Id: **361224-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Aug-2007	24-Jul-2009	708	16-Oct-2009	30-Oct-2009	OH		02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure increased, Contraception, Menorrhagia, Pain, Polycystic ovaries, Pyrexia

Symptom Text: After receiving the Gardisal vaccine, my daughter went from having no pain during menestration to developing poly- cystic ovaries, she now has to be on the birth control pill to control the exttreme pain(which was so bad, it caused her blood pressuire to rise, and her to develope a fever),and heavy bleeding involved in this disorder.

Other Meds: albuterol inhaler as needed

Lab Data: x-ray performed at the emegency room, ultra sound done at the gynecologist

History: asthma

Prex Illness: none

Prex Vax Illns:

Vaers Id: **361227-1 (S)** **Related reports:** 361227-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	17-Aug-2009	30-Sep-2009	44	16-Oct-2009	20-Oct-2009	TX		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	3	Left arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Arachnoid cyst, Areflexia, Asthenia, Back pain, Blood product transfusion, Endotracheal intubation, Guillain-Barre syndrome, Haemodialysis, Haemothorax, Headache, Hypoaesthesia, Hypoaesthesia oral, Influenza like illness, Intensive care, Muscular weakness, Plasmapheresis, Pleural effusion, Pneumonia, Respiratory failure, Sepsis, Staphylococcal infection, Tracheostomy

Symptom Text: ascending paralysis, resp failure requiring intubation, IVIG x5 days followed by plasmapheresis x5 days. patient remains intubed and in ICU 10/22/09 Hosp. records received for dates 10/1/09 to 10/18/09. Current DX: GBS. Pt. presented to ER on 10/1/09 with c/o numbness in all extremities, pain, weakness in legs, back pain, numbness in mouth. Pt. was in ER 1 day prior and sent home, sx. Increased pt. returned to ER. Pt c/o flu like sx 10 days prior. pt received gardasil vax 8/17/09. Assessment: WNL except, absent knee reflexes, hypoflex of lower extremities. (+)intramuscular fluid around spine at the occipital cervical junction. DX at time of assessment: GBS vs. idiopathic polyneuropathy vs. MS. Pt. admitted to medical unit, sx. deteriorated transferred to ICU. Further assessments: absent deep tendon reflexes of upper and lower extremities, c/o pain throughout entire spine. MRI of spine (+)arachnoid cyst. 10/5/09 pt. intubated, tx IVIG with no response. Plasmapheresis. DX: GBS, respiratory failure, hemothorax. 10/15 tracheotomy placed. ```DC summary and hosp recs received 2/1/10 for 10/1/09 to 10/22/09. DX: GBS, ascending paralysis, respiratory failure, hemothorax secondary to hemodialysis cath, bilat pneumonia, staphylococcus aureus septicemia, rt pleural effusion. Pt was admitted for c/o numbness/tingling in her feet which progressed to legs, then hands, then weakness in her legs, and difficulty walking, HA, backaches. Assessment: neuro exam abnormal, diminished sensation, deep tendon reflex diminished

Other Meds: YAZ

Lab Data: 10/22/09 Hosp. records received for dates 10/1/09 to 10/18/09 Diagnostics/Labs: EKG sinus tachycardia, DVT(-), abdominal US(-), CXR abnormal-LLL infiltrates, CT chest(-), LP abnormal-CSF protein(H), CSF glucose(H), CSF WBC(H), CSF ALB 9(L),

History: none 10/22/09 Hosp. records received for dates 10/1/09 to 10/18/09 PMH: anemia, previous smoker, family history of GBS.

Prex Illness: no

Prex Vax Illns:

Vaers Id: **361227-2 (S)** **Related reports:** 361227-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	17-Aug-2009	30-Sep-2009	44	15-Jan-2010	19-Jan-2010	--	WAES0912USA00176	19-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	3	Left arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Arachnoid cyst, Areflexia, Asthenia, Back pain, Blood product transfusion, Endotracheal intubation, Guillain-Barre syndrome, Haemothorax, Hypoaesthesia, Hypoaesthesia oral, Influenza like illness, Intensive care, Multiple sclerosis, Muscular weakness, Pain, Plasmapheresis, Polyneuropathy idiopathic progressive, Reflex test abnormal, Respiratory failure, Sinus tachycardia, Tracheostomy

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 26 year old female with a history of anaemia, previous-smoker and family history of GBS, on 17-AUG-2009 was vaccinated with a fourth dose of GARDASIL (lot # 662404/0312Y, route unknown) in the left arm. Concomitant therapy included YAZ. On 30-SEP-2009 the patient experienced arachnoid cyst, areflexia, asthenia, back pain, blood product transfusion, endotracheal intubation, Guillain-Barre syndrome, haemothorax, hypoaesthesia, hypoaesthesia oral, influenza like illness, intensive care, muscular weakness, plasmapheresis, reflex test abnormal, respiratory failure and tracheostomy. The patient experienced ascending paralysis, respiratory failure requiring intubation. She had IVIG (intravenous immunoglobulin) for 5 days followed by plasmapheresis for 5 days. The patient remained intubed and was in ICU (intensive care unit). On 22-OCT-2009 Hospital records were received for dates 01-OCT-2009 to 26-OCT-2009. The patient was currently diagnosed as GBS (Guillain-Barre syndrome). On 01-OCT-2009 the patient presented to ER with complaint of numbness in all extremities, pain, weakness in legs, back pain, numbness in mouth. Patient was in ER 1 day prior and sent home. Symptoms increased patient returned to ER. The patient complained of flu like symptoms 10 days prior. Assessment: WNL (Within normal limits) except, absent knee reflexes, hypoflex of lower extremities (+) intramuscular fluid around dpine at occipital cervical junction. The patient's diagnoses at time of assessment were GBS vs idiopathic polyneuropathy vs MS (Multiple Sclerosis). Patient was admitted to medical unit, symptoms deteriorated and she was transferred to ICU. Further assessments: absent deep tendon reflexes of upper and lower extremities, complaint of pain throughout entire spine. MRI of spine (+) arachnoid cyst. On 05-OCT-2009 the patient was intubated, and treatment with IVIG, no response. The patient had lab test of P

Other Meds: YAZ

Lab Data: Electrocardiogram, 10/??/09, sinus tachycardia; Diagnostic laboratory, 10/??/09, Deep venous thrombosis negative; Abdominal ultrasound, 10/??/09, negative; Chest X-ray, 10/??/09, abdominal-LLL infiltrates; Chest computed axial, 10/??/09, ne

History: Anaemia

Prex Illness: Ex-smoker; familial risk factor

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361228-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	07-Oct-2009	07-Oct-2009	0	16-Oct-2009	26-Oct-2009	TX		26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0980Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Limb discomfort, Pain

Symptom Text: Patient complains of pain in her left arm at the injection site since receiving her first dose of Gardasil on 10/7/2009. She first reported this complaint to our office on 10/14/2009 and stated that the pain was worse with movement and she was experiencing difficulty using her left arm due to the discomfort, and she was advised to try ibuprofen and heat. She returned to our office on 10/16/2009 for evaluation and reports that ibuprofen has not provided adequate relief and heat made the pain worse. Upon examination, there is no erythema or swelling at the site and no tenderness to palpation. There is full range of motion and normal grip and fine motor movement in both hands. She was given a prescription for a non-steroidal anti-inflammatory medication and will follow up next week to report on her condition.

Other Meds: ibuprofen

Lab Data: none

History: fibrocystic breast changes; allergic to Vicodin (causes nausea)

Prex Illness: none

Prex Vax Illns:

Vaers Id: **361290-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Oct-2009	15-Oct-2009	0	16-Oct-2009	19-Oct-2009	TN		11-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	500723P		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Convulsion, Immediate post-injection reaction, Syncope

Symptom Text: Fainting, seizures immediately following vaccination. 10/19/09 Emergency Department records received for date of serivice 10/15/09. Dx: Syncope, seizure, anxiety Assessment: Seen for syncopy vs. seizure episode. EEG, Head CT and Echo normal. Head CT: No evidence of intracranial process. Echo: Normal study.

Other Meds:

Lab Data: EEG, EKG, CT SCAN, ECHO CARDIOGRAM, MRI. 10/19/09 Emergency Department records received for date of serivice 10/15/09. Labs and disgnostics: EEG: WNL, MCV 78.1 (L), RDW 15.8 (H), Urine Drug screen-Negative. Urine PH 7.5 (H), Urine bact

History: NONE. 10/19/09 Emergency Department records received for date of serivice 10/15/09. PMH: None.

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361318-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Oct-2007	20-Oct-2007	0	17-Oct-2009	21-Oct-2009	FL		17-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anxiety, Autonomic nervous system imbalance, Blindness, Chest pain, Convulsion, Deafness, Depression, Dizziness, Ear pain, Faecal incontinence, Fatigue, Headache, Hyperhidrosis, Hypertension, Injection site pain, Insomnia, Loss of consciousness, Menstruation irregular, Migraine, Muscular weakness, Myalgia, Nausea, Orthostatic hypotension, Pain in extremity, Palpitations, Panic reaction, Papilloedema, Paraesthesia, Postural orthostatic tachycardia syndrome, Quality of life decreased, Sinusitis, Syncope, Tachycardia, Urinary incontinence

Symptom Text: severe pain at injection site, since that time has started blacking out, seizures, migraines, heart palpitations, blood pressure control problems, nausea, severe pain in extremities, tingling in arms and legs,severe tiredness, low quality of life. 11/4/09 Medical records received for date 6/5/08 to 10/28/09. 6/5/08 Pt established care at PCP with initial c/o multiple syncopal episodes in past few wks. Mostly when changing positions lying/sitting. DX: syncope, irreg. menses, sinusitis, insomnia. Multiple OV for c/o syncope, body aches, dizziness, chest pain, ear pain, DX: syncopal episodes, orthostatic HTN, muscle pain, chest pain, tachycardia, depression/anxiety, autonomic dysfunction. ```2/8/10 Neuro records received for DOS 8/12/09-9/14/09 with dx: Suspected autonomic nervous system dysfunction; consider POTS syndrome. Recurrent syncope. Hx- anemia. Hx-dysfuctional uterine bleeding. Hx-anxiety and depression. Neuro review of other records show episodes of bowel and bladder incontinence of unknown etiology as well as papilledema and chronic daily H/A. Pt dx with orthostatic hypotension. Pt has had 3 seizures. Episodes begin with sweating, dizziness, loss of vision and hearing, panic, then passing out. Also reports bilateral LE pain, weakness. Initially suspected neurocardiogenic syncope vs autonomic dysfunction.

Other Meds:

Lab Data: MRI, MRV, CAT SCANS, numerous blood work studies, EEG, EKG, Holt monitor, tilt table testing.```Labs and Diagnostics: holter monitor (-). Transthoracic echo (-) . MRI/MRA brain (-). EEG (-). MRI lumbosacral spine (-). Tilt table test (+

History: allergic codeine, pcn ```PMH: obesity, HTN, allergy to PCN, Aleve, codeine, solumedrol. Menorrhagia, sinusitis, left breast nodule.

Prex Illness: none

Prex Vax Illns:

Vaers Id: 361356-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	09-Sep-2009	02-Oct-2009	23	16-Oct-2009	21-Oct-2009	CA		10-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	2	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Areflexia, Arrhythmia, Asthenia, Autonomic nervous system imbalance, Babinski reflex test, Bradycardia, Dizziness, Electrocardiogram normal, Herpes simplex, Hyperhidrosis, Hypoaesthesia, Neuropathy peripheral, Nuclear magnetic resonance imaging abnormal, Orthostatic hypotension, Panic reaction, Paraesthesia, Steroid therapy

Symptom Text: 10/14/09 Report from pt via phone call. On 10/2, awakened feeling okay - went to bathroom. While on toilet had sudden onset of numbness in upper back and across "shoulder blades". Walked to bed - laid down - rapid progression to "sweating", "panic" feeling and sensation of "blacking out". 911 called. Rapid progression of tingling - eventual numbness to legs. Admitted to ER - and hospitalization. Pt continues to recover. At this writing is able to walk with assistance. 11/2/09 ICD-Codes received: 356.9 Idio Peripheral Neurpthy NOS, 341.20 Acute (Transverse) Myelitis NOS, 054.9 Herpes Simplex NOS, 427.89 Cardiac Dysrhythmias NEC, 458.0 Orthostatic Hypotension. 11/5/2009 Discharge summary and lab results received for DOS 10/02/09-10/04/09. Final DX: Transverse myelitis with residual bilateral upper extremity weakness. Improving. Orthostatic hypotension. Patient woke up with tightness in upper back. Weakness in L arm. Weakness, numbness. Progressed to lower extremities. Felt faint and cold sweats. Tingling. Strength decreased UE (1-2/5). Could not lift arms off bed. LE sensation diminished. Decreased sensation across chest wall. DTR decreased all four extrem. Neg Babinski bil. Extensive herpes simplex cold sores. Bradycardia and postural hypotension autonomic dysfunction s/t CNS problem. EKG WNL. MRI abnormal. Steroid therapy. Improved. Transfer to rehab facility.

Other Meds: Supplements; Multivitamins; Primrose; Glucosamine; Vit C

Lab Data: Indicates dx: Transverse Myelitis - ? etiology. LABS and DIAGNOSTICS: MRI thoracic spine: T2 hypersensitivity within the visualized portion of lower cervical spinal cord. Bld CX no growth. WBC 22.2 (H), neutr 88 (H), lymph 3 (L), monocy 1(

History: None. PMH: cannabis use. Allergies: None.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361413-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	10-Aug-2009	11-Aug-2009	1	19-Oct-2009	29-Oct-2009	MI		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0314Y		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal haemorrhage

Symptom Text: On OC with good cycle. Started bleeding after GARDASIL. Bled rest of cycle - Moderate, needed maxi pads (happened to a friend also).

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **361427-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	09-Jul-2008	Unknown		19-Oct-2009	22-Oct-2009	MA		24-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Asthenia, Attention deficit/hyperactivity disorder, Chest pain, Cough, Diarrhoea, Fatigue, Gastrointestinal disorder, Haematochezia, Lymphadenopathy, Oropharyngeal pain, Pain, Pain in extremity, Pyrexia, Restless legs syndrome, Weight decreased

Symptom Text: 09/2008 GASTROINTESINAL PROBLEMS 10/2008 WEIGHT LOSS 11/2008 SWOLLEN GLANDS LEG PAINS/RESTLESS LEGS LOST 30 LBS IN 3 MONTHS/TIRED FATIGUE/WEAKNESS -CONTINUED UNTIL PRESTENT DAY ```1/20/10 Primary care records received for dates of service 3/26/09 to 6/24/09. Dx: Weight loss, fatigue, anxiety, Attention Deficit Disorder. Presented with cough, body aches, fever, burning in chest, sore throat, weight loss, blood in stool and diarrhea.

Other Meds:

Lab Data: ENDOSCOPY, COLONOSCOPY, TONSILECTOMY, BLOOD WORK, SWALLOWED CAMERA. ```2/16/10 Colonoscopy record received from date of service 12/2/08. Labs and diagnostics: Normal colon. ```2/16/10 Hand Xray from date of service 11/30/09. Labs a

History: NONE. PMH: ADD, Anxiety, Heart Murmur, tonsilectomy.

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **361431-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-Sep-2009	29-Sep-2009	0	19-Oct-2009	20-Oct-2009	UT	WAES0910USA00978	25-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU	UNKNOWN MANUFACTURER	U3186AA		Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0671Y	1	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3249AA		Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0492Y	2	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Physical examination normal, Syncope, Tonsillar inflammation, Upper respiratory tract infection

Symptom Text: Information has been received from a physician concerning a 13 year old female who on an unspecified date, was vaccinated with the first dose of GARDASIL. The patient was concomitantly vaccinated with VARIVAX (MSD) and tetanus toxoid. The patient fainted after receiving GARDASIL and had a brief seizure. The patient sought unspecified medical attention. The patient has recovered. Upon internal review brief seizure was determined to be an other important medical event. Additional information has been requested. 12/30/2009 PCP office note, telephone encounter records and immunization record received for DOS 09/17/1997-11/17/2009. DX: Well infant/child exam, URI Patient presented with no complaints. Examination revealed oropharynx and tonsils mild red, not swollen, no exudate. Received Varicella #2, TDap (Adacel), HPV#1 and Influenza 3+ years. After office visit, mother reported patient passed out in parking lot, appeared to have a seizure but was fine and did not need to be seen.

Other Meds:

Lab Data: Unknown

History: 12/30/2009 PMH: Asthma, seasonal allergies, pneumonia (02/98).

Prex Illness: URI

Prex Vax Illns:

Vaers Id: 361432-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	19-Feb-2008	21-Feb-2008	2	19-Oct-2009	20-Oct-2009	--	WAES0910USA01159	04-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Balance disorder, Dysarthria, Hypoaesthesia, Menstruation irregular, Multiple sclerosis, Paraesthesia, Paralysis, Reflex test abnormal, Vision blurred

Symptom Text: Information has been received from a healthcare worker concerning a 25 year old female patient with no pertinent medical history and no known allergies who on an unspecified date was vaccinated with the first dose of GARDASIL (lot number not reported). The patient was new to the practice and the vaccine was not given in this practice. 2 days after the vaccination, the patient developed numbness to her left side. About 2 weeks after the onset of those symptoms, the patient was diagnosed with Multiple Sclerosis (MS). The patient saw family physician and neurologist (date unspecified). It was unknown if there were lab studies performed. At the time of the report, the outcome of the patient was not reported. Multiple sclerosis was considered to be disabling by the reporter. Follow-up information received from a medical assistant (MA) concerning the 23 year old (previously reported as 25 years old) female patient who on 19-FEB-2008 was vaccinated with the first dose of GARDASIL (lot number not reported). The MA did not know the physician's name where the patient received the vaccine. On 05-FEB-2009, the patient was first seen in the office for irregular bleeding. On MAR-2009 the patient was seen again and the irregular bleeding had resolved. Additional infoformation has been requested. 10/23/2009 records from Neurologist, multiple visits 3/2008-7/2009. Patient's sx started 2/2008 with numbness/tingling, inbalance, slurred speech, blurred vision and paralysis, LUE and LLE. PE noted hyperreflexia bilaterally, Romberg's sign absent. Dx MS

Other Meds: Unknown

Lab Data: Unknown Labs: CBC WNL, CMP glucose 141 High Dx studies: Visual evoked response study to r/o optic neuropathy was negative studies mentioned but with no results: RA factor, ANA, IEP, RPR, TSH, UA, ESR, Folic acid, Vit B12 MRI Brain and E

History: None PMH: None Allergies: NKDA

Prex Illness:

Prex Vax Illns:

Vaers Id: 361433-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jun-2009	01-Jun-2009	0	19-Oct-2009	20-Oct-2009	FR	WAES0910USA01676	20-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Rash, Rash maculo-papular

Symptom Text: Information has been received from a Gynecologist concerning a 15 year old female patient with herpes simplex who in June 2009, was vaccinated with the first dose of GARDASIL (Batch # not reported) into her arm. Secondary suspect vaccine given in June 2009 in the other arm included a dose of ENGERIX-B (exact date not provided). Other concomitant therapy included ZELITREX. It was reported that a few hours after vaccination, she was hospitalized due to a generalized maculo papular exanthema. The patient received an unspecified treatment. It was reported that tests and work-ups were performed (results not provided). To be noted that at the time of vaccination, the patient was treated with ZELITREX for an ongoing herpes simplex. The hospital contraindicated to continue the vaccination with GARDASIL and ENGERIX-B. To be noted that the reporter did not see the patient at the time of the event, but only read a letter from the hospital. At the time of reporting, the patient had recovered. Other business partner numbers include: E2009-09559. No further information is available.

Other Meds: ZELITREX

Lab Data: Unknown

History:

Prex Illness: Herpes simplex

Prex Vax Illns:

Vaers Id: **361548-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	05-Oct-2009	13-Oct-2009	8	19-Oct-2009	29-Oct-2009	MA		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0670Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Sensory disturbance

Symptom Text: Pt states as 10/13 "pulsing". Feeling on inner aspect of L arm.

Other Meds:

Lab Data: none

History: h/o depression

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361580-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	16-Oct-2009	16-Oct-2009	0	19-Oct-2009	28-Oct-2009	TN		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Decreased appetite, Diarrhoea, Headache, Hypokinesia, Muscle spasms, Nausea

Symptom Text: Headache, severe nausea, loose stools, hand cramps, unable to move fingers, loss of appetite, weakness

Other Meds: Fluconozole

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361604-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Oct-2009	16-Oct-2009	0	19-Oct-2009	28-Oct-2009	CA		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLUA448BA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0558X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site swelling, Injection site warmth

Symptom Text: 10/16/09 @ 4:00 PM patient given flu vaccine. Within the minute patient mention lump & hotness. Immediately called Dr. for observation on left arm.

Other Meds:

Lab Data:

History: Allergic to AMOXICILLIN.

Prex Illness:

Prex Vax Illns:

Vaers Id: 361628-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-May-2009	18-Sep-2009	121	20-Oct-2009	21-Oct-2009	--	WAES0910USA01852	23-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arrhythmia, Chest pain, Dyspnoea, Syncope, Tachycardia

Symptom Text: Information has been received from a health professional who reported that a male with a family history of ventricular arrhythmia, on an unspecified date was vaccinated with GARDASIL. Subsequently the patient experienced an unspecified arrhythmia arrhythmia. On an unspecified date the patient died. The cause of death was not reported. This is one of several reports received from the same source. No further information is available. 10/29/09 Medical records received for date 9/18/09. DX: episodic chest pain, dyspnea, and syncope. Ectopic atrial tachycardia documented on one occasion. Presenting SX: chest pain, syncope f/u eval. Pt states most recent episodes x2 9/09. Pt. states develops chest pain shortness of breath, then syncope, pulse taken, 160bpm. Pt states feel increase in HR with these episodes. Pt parent states sx. began in 5/09 after gardasil vax. Assessment: cardiac:WNL will order holter monitor. 12/9/09-it was learned that the pt did NOT die.

Other Meds: Unknown

Lab Data: 10/29/09 Medical records received for date 9/18/09. Diagnostics/Labs: CT thorax WNL, Coronary CT angiography-borderline enlarged rt. atrium. w/ contrast-WNL.

History: Unknown 10/29/09 Medical records received for date 9/18/09. PMH: none

Prex Illness:

Prex Vax Illns:

Vaers Id: **361629-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		20-Oct-2009	21-Oct-2009	--	WAES0910USA00269	27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, ER VISIT, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from an office manager and a consumer who reported that she had seen reports of deaths following GARDASIL on television. This is one of two cases from the same source. This is a hearsay report in the absence of an identifiable patient. All telephone attempts to obtain follow up information have been unsuccessful.

Other Meds: Unknown

Lab Data: Unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 361631-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	29-Sep-2009	07-Oct-2009	8	20-Oct-2009	21-Oct-2009	FR	WAES0910CAN00044	21-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Myalgia, Paraesthesia

Symptom Text: Information has been received from a female who on 29-SEP-2009 was vaccinated with the first dose of GARDASIL, lot # not available. On 07-OCT-2009 the patient experienced tingly numbing feeling in quads (only her quads not her hamstrings, calves or feet) and tender muscles (whenever she would apply pressure to her quads). The patient reported that it felt like her legs were starting to wake up after being "asleep". On 08-OCT-2009 the patient recovered from tender muscles. On 09-OCT-2009 the patient recovered from tingly numbing feeling in quads. Tingly numbing feeling in quads was determined to be an important medical event based on agency requirement. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **361632-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-May-2009	27-May-2009	0	20-Oct-2009	21-Oct-2009	FR	WAES0910USA00964	21-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X		Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Dyspnoea, Fatigue

Symptom Text: Information has been received from a health professional through the HPV access program (GAP) concerning a patient who on an unspecified date was vaccinated with GARDASIL. Subsequently, the patient had an adverse experience managed well with antihistamines. Follow-up information was received from a health professional concerning a 16 year old female who on 27-MAY-2009 was vaccinated with GARDASIL (Lot# 662229/1497X) intramuscularly in the right deltoid muscle. On 27-MAY-2009, the patient also received epinephrine (Lot# 90BD229). On 27-MAY-2009 at 15:30, the patient experienced fatigue, weakness and shortness of breath. The patient was hospitalized. The patient's outcome was not reported. The reporter felt the patient's experience was related to therapy with GARDASIL. Additional information is not expected.

Other Meds: epinephrine

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 361633-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jun-2008	04-Jun-2009	368	20-Oct-2009	21-Oct-2009	FR	WAES0910USA01637	02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Autoimmune hepatitis, Hepatic necrosis, Incorrect route of drug administration, Jaundice

Symptom Text: Initial case was reported as a misuse and as a serious case on 13-OCT-2009 by health authority (HA reference # FI-NAM-20090982). It was reported that a 17 year old female on an unspecified date in September 2008 was vaccinated subcutaneously with a 0.5ml dose of GARDASIL (lot#, number in series and site of administration not reported). Concomitant therapy included MERCILON beginning from 01-JAN-2009, tablet, indication of use not specified by primary reporter, a physician). The case was a misuse case as GARDASIL was administered subcutaneously instead of intramuscular administration. On 04-JUN-2009 the patient was diagnosed with icterus and liver necrosis size of 20-30. Her laboratory values in autoimmune serology including IgG value and in virus serology were normal which were examined on unspecified date(s). The patient was hospitalized on unspecified date for unspecified period. The treatment (trade name or generic name not reported) against autoimmune hepatitis was started on unspecified date. The patient gave first good response to the treatment against hepatitis but later again (on unspecified date) there was increase in values of liver enzymes and synthesis was decreased. The status of patient is suitable for either toxic or autoimmune hepatitis according to the primary reporter. There was over 6 months latency between the last dose of the vaccine and liver disease but otherwise the causality to the vaccine was possible according to the primary reporter. Patient's medical history included that on 01-JUN-2008 she was vaccinated subcutaneously with a 0.5ml dose of GARDASIL (lot#, number in series and site of administration not reported). It was reported by the primary reporter that vaccines doses were given between 2 months intervals. The total amount of vaccine administered was not reported. The MedDra coding of the case by the Health Authorities was not provided to the MA-holder. The outcome was not yet recovered defined by primary reporter. Hepatitis was also considered to a congenital anomaly. There was

Other Meds: MERCILON

Lab Data: enzyme supplementation, decreased; serum immunoglobulin G test, normal; clinical serology test, normal; viral culture, normal; hepatic function tests, increased

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361659-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Oct-2009	13-Oct-2009	1	20-Oct-2009	30-Oct-2009	KY		28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0912Y	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	06724	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3044AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3246BA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1005Y	0	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site cellulitis

Symptom Text: Received VARICELLA 10-12-09 left arm. Now has cellulitis 10.4 cm X 10.1 cm area. Rx BENADRYL & CLINDAMYCIN.

Other Meds:

Lab Data: Cellulitis.

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361663-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Oct-2009	20-Oct-2009	0	20-Oct-2009	26-Oct-2009	SC		27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U3091AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0819Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Feeling hot, Flushing, Hyperhidrosis, Pallor, Vomiting

Symptom Text: The mother stated the child complained of feeling hot, became flushed and diaphoretic, and consequently vomited. After vomiting, the pt was pale. Blood pressure after incident 85/52 and BP 30 later was 98/58

Other Meds: Singulair 5mg chewable tab ventolin HFA Flonase

Lab Data:

History: asthma, allergic rhinits, ADD w/o hyperactivity

Prex Illness: no

Prex Vax Illns:

Vaers Id: **361718-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Sep-2009	22-Sep-2009	0	20-Oct-2009	30-Oct-2009	IL		18-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphthous stomatitis, Dermatitis, Hypersensitivity, Lip swelling, Oral pain, Rash generalised, Toothache

Symptom Text: Pt experienced lip swelling, total body rash and aphthous ulcers and tooth and mouth pain. ```MR received on 01/12/10 for DOS 09/03/09, 10/19/09. Pt c/o aphthous ulcers, allergic skin rash, dermatitis. Tx: steroids and antihistamine meds. Assessment: Allergic reaction to Gardasil. On 10/19/09, Pt presented for F/U visit and event reported resolved.

Other Meds:

Lab Data:

History: Pt had similar response to first dose, mom released after 1st shot given (per mom, given at another clinic)

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361742-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Oct-2009	07-Oct-2009	1	20-Oct-2009	30-Oct-2009	FL		11-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2874BA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Pain in extremity

Symptom Text: Pain and swelling of hands and feet - mild but uncomfortable - no 1 or at injection site inflammation swelling or discomfort no rash, fever or other symptoms.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361775-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Jun-2008	26-Jun-2008	0	20-Oct-2009	31-Oct-2009	NY		11-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0755U	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2643AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Nausea, Oedema peripheral

Symptom Text: Right arm swelled developed a temp, nausea for 2 days after GARDASIL vaccine. We were not notified until 10/12/09 about reaction.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Sep-2009	30-Sep-2009	0	20-Oct-2009	03-Nov-2009	TN		25-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	08194	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis contact, Eye swelling, Oral pruritus, Pruritus, Rash, Swelling face

Symptom Text: My 12 year old daughter received her second Gardasil shot Wednesday, September 30, 2009. She complained of her tongue itching later that night. I started giving her Zertec. The next day she was complaining of itching on her face around her eye. I gave her Zertec twice a day until Friday night when she developed a rash on the right side of her face around her eye. At that point I started giving her Benadryl every four hours. Her face was significantly swollen on the right side by Saturday night. Sunday morning, her eye was swollen nearly shut. The right side of her face was swollen so severely, she was unrecognizable from her profile. I applied cool compresses, continued Benadryl, and gave Tylenol for the discomfort. I tried to get an after-hours appointment but was told by the on-call nurse to continue the Benadryl and that unless she had blister, there was no reason to see the doctor. Monday AM her eye was completed swollen shut, and her skin was so tightly swollen the itching had subsided. I did get her a doctor's appointment that afternoon but was told it was contact dermatitis, and that it had nothing to do with the second Gardasil shot that she had five days earlier. I asked the doctor to document the possibility that it was a reaction to the shot in her records. She said it was worth noting but that she had not seen any such reactions. (I do not believe she documented it.) She prescribed 60mg of Prednisone a day for five days and told me to continue to give her the 50 mg of Benadryl every four hours. By Monday night the very raw irritable rash had spread to the other side of her face. Tuesday the swelling on the right side had lessened but her cheek and eye were still puffy and the hives were still very raw. Tuesday night the rash had spread to cover most of the left sides of her face, behind both ears toward the back of her neck, and under her chin, down her neck and onto her chest. I continued to following doctor's instructions giving her the Benadryl and Prednisone. Wednesday morning the redness had subs

Other Meds: N/A

Lab Data: .```1/19/2010 PCP records Dx Allergic reaction None

History: Ezcema .```1/19/2010 PCP records Dx Allergic reaction PMH: None Allergies: NKDA

Prex Illness: N/A .```1/19/2010 PCP records Dx Allergic reaction

Prex Vax Illns: chicken pox~Varicella (no brand name)~1~2.00~Patient

Vaers Id: **361885-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Oct-2009	20-Oct-2009	0	20-Oct-2009	27-Oct-2009	IN		28-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB327AA	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3161CA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2910AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysstasia, Fall

Symptom Text: Sitting in chair; Started to stand up 10 minutes after shot and fell forward to floor

Other Meds:

Lab Data: BP 90/50. Pulse ox 95. Heart Rate 66

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **361892-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Oct-2009	20-Oct-2009	0	20-Oct-2009	28-Oct-2009	CT		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fear of death, Nausea, Pain, Pallor, Presyncope

Symptom Text: The patient complained of intense pain, became pale and appeared to have a near syncopal event. She then complained of nausea, felt she was going to vomit but did not and was afraid she was going to die. She was examined, all vitals were stable, and reassurance was provided. The patient felt better and left the office with no further complaint after approximately 30 minutes

Other Meds:

Lab Data: none

History: NO

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **361899-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Feb-2006	27-Feb-2006	20	20-Oct-2009	29-Oct-2009	PA		12-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	02138AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Autonomic nervous system imbalance, Cold sweat, Concussion, Depressed level of consciousness, Dizziness, Loss of consciousness, Panic attack, Pulse pressure decreased, Syncope, Unresponsive to stimuli, Vision blurred

Symptom Text: Patient would stand up in assembly and feel faint these progressively got worse where she passed out on a lacrosse field and soccer fields and was for a brief time unresponsive,concussions did occur with 2 of these episodes. Her pulse at times was weakly palpable and it would take minutes to arouse her. These epiodes got worse and more frequent after each dose of Gardasil. She was seen by cardiologist had 2 tilt table test, had cardiac monitoring and EEG. She was placed on beta blockers florinef and mitodrine. Nothing worked episodes increased all thru high school she was forced to quit sports. Till this day in elevators, hot situations close quarters she will faint. She is off all medicines because her cardiologist saw no improvement. 10/29/09: Vaccination record received, VAERS updated. ```12/29/09 Office visit notes and labs received for dates of service 10/16/08 to 8/20/09. Dx: Dysautonomia with hypervagal response and paradoxic parasympathetic activity. Episodes of dizzy spells, becomes clammy, blurring vision and frank syncope. Also has panic attacks and anxiety.

Other Meds:

Lab Data: 11/06/07 tilt test weakly positive cardiac stress test positive Lab test cortisol 15.4 hgb 11.7 hct 34.4 ekg showed sinus tachycardia of 198 with an episode. ```12/29/09 Office visit notes and labs received for dates of service 10/16/08

History:

Prex Illness: Was being evaluated for feeling lightheaded in the assembly at school

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361918-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	12-Aug-2009	12-Aug-2009	0	20-Oct-2009	31-Oct-2009	OR		01-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0206Y	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0805Y	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2919AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope, (awoke on own within 30 sec).

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **361971-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	21-Apr-2009	01-Aug-2009	102	21-Oct-2009	04-Nov-2009	--		08-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Urticaria, Urticaria thermal

Symptom Text: My daughter was only 10 years old when she got vaccinated with GARDASIL. She is now suffering from cold urticaria, also called cold, hives, because of GARDASIL. THis will affect her entire life. Because of this horrible side effect, she can not do many things that she used to. For example, she will not be able to be in the swimming team, because everytime she gets in the cold water she gets hives. When she goes out in the cold weather, she gets hives. The hives are red small and large bumps that itch terribly and come out all over her body, including her legs, stomach, back and arms. They last from a whole day to almost a week sometimes. I do not recommend anyone take this vaccination and a warn parents to not let their chidren doctor convince them to take it. I regret ever letting them give this shot t my daughter, but I was told it was s mandatory shot that needed to be given in order for my daughter to go to school. ```Vaccine records indicate 2nd dose of Gardasil Merck 0381X on 8/12/2009, Deltoid Rt. \ksk

Other Meds:

Lab Data: Diagnosed on 2/2/2009

History: Cold Urticaria

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362006-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Oct-2009	21-Oct-2009	0	21-Oct-2009	02-Nov-2009	FR		02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Diarrhoea, Pyrexia

Symptom Text: fever, diarreha, stomach ache

Other Meds:

Lab Data:

History:

Prex Illness: ingrown toenail infection

Prex Vax Illns: large swelling of arm~Influenza (Seasonal) (no brand name)~1~6.83~Patient

Vaers Id: **362041-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	07-Oct-2009		21-Oct-2009	22-Oct-2009	--	WAES0910USA01727	22-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Loss of consciousness, Tremor

Symptom Text: Information has been received from a nurse practitioner's and an office receptionist concerning a 13 year old female patient who was vaccinated "sometime last week" with a dose of GARDASIL (Lot # not provided). Concomitant therapy included influenza virus vaccine (unspecified). Receptionist reported that the patient received a dose of GARDASIL and a dose of influenza virus vaccine (unspecified). Immediately after receiving the GARDASIL the patient passed out and had a shaking seizure which ended quickly. No ill effects since then. Upon internal review, shaking seizure was determined to be another important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362044-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		21-Oct-2009	22-Oct-2009	FR	WAES0910USA02087	22-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthritis, Erythema nodosum, Lymphadenopathy

Symptom Text: Case received from a health care professional on 13-OCT-2009. It was reported by an internist that a 1992 born female patient was vaccinated with a second dose of GARDASIL (lot #, injection site and route not reported) on an unspecified date in 2008. Shortly post vaccination (no exact date reported) the patient experienced erythema nodosum, arthritis and swollen lymph nodes (not specified). A prior lymph node biopsy showed no pathologies but due to ongoing symptoms since a year, a further biopsy and diagnostic clarification were intended. The patient was vaccinated with the first dose of GARDASIL on an unknown date, toleration was not reported. Other business partner numbers include E2009-09496.

Other Meds: Unknown

Lab Data: lymphatic structure biopsy, no pathologies

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362052-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Aug-2009	10-Aug-2009	0	21-Oct-2009	22-Oct-2009	FR	WAES0910USA02089	22-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0772X	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Depressed level of consciousness, Headache

Symptom Text: Case received by Health Authority (case n. 104529) through (local case n. IT420/09). Initial report received on 13-OCT-2009. On 10-AUG-2009 a 12 year old female patient with no previous medical history was vaccinated intramuscularly with the third dose of GARDASIL (lot # 0772X, batch # NK15900). On the same day she presented with headache and sensory obnubilation. She was admitted to the hospital. The outcome is recovered on 11-OCT-2009. The case is closed. Other business partner numbers include E2009-09521.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 362076-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	31-Aug-2009	10-Sep-2009	10	21-Oct-2009	26-Oct-2009	VA		17-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	1	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Contusion, Convulsion, Epilepsy, Grand mal convulsion, Memory impairment, Nausea, Petit mal epilepsy, Vomiting

Symptom Text: Grand Mal Seizure ``` records received 02/02/2010. Lab report for 03/10/06 and PCP Clinic rec. for DOS 06/06/08- 08/31/09. Rec. document HPV on 06/30/09 and 08/31/09. No complaints offered. ```2/12/10 ED Record received for date of service 9/11/09. Dx: Seizure. Vomiting. Presents for evaluation of grand mal seizure the night before, nausea and vomiting. Onset was sudden, lasted less than one minute, single episode. Pt. fell with left patella contusion. Last seizure prior to that was in 2005. Treated with phenergan and valium. Discharged home in stable condition. Describes short term memory loss after HPV vaccine. ```records received 02/15/2010. Clinic out-patient notes for DOS 09/15/09 & 10/30/09. Assessment: Primary epilepsy. Return office visit: Patient followed for epilepsy, who recently had seizure in context of having HPV vaccine. Patient was given extra dosages of Lamictal and Valium and now patient feels "like she is back to herself". EEG today. Return visit: Patient c/o a petit mal seizure, while drinking diet soda. It stopped immediately, when she stopped drinking the soda. Plan: follow-up if continues to have breakthrough and consider med. adjustments.

Other Meds:

Lab Data: ```2/12/10 ED Record received for date of service 9/11/09. Labs and diagnostics: HCG-Negative. Total protein 8.5 (H), Albumin 5.4 (H). Segs. 81 (H), Lymphocytes 12 (L). CT Head-no acute intercranial process. UA, Leukocyte esterase-Trac

History: Epilepsy ``` 02/02/2010 PMH: NKA, ADD, seizure disorder, abnormal pap smear, rash on feet.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 362167-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Aug-2009	20-Aug-2009	0	22-Oct-2009	02-Nov-2009	TX		02-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MMR	MERCK & CO. INC.	1366X	1	Left arm	Subcutaneously	
DTAP	SANOFI PASTEUR	C3246BA	5	Right arm	Intramuscular	
HEPA	MERCK & CO. INC.	1584X	1	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0884Y	1	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2990AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Antibiotic therapy, Headache, Hypotonia, Influenza serology negative, Muscle twitching, Nausea, Pain in extremity, Syncope, Tachycardia, Unresponsive to stimuli, Viral infection

Symptom Text: PATIENT FAINTED AFTER RECEIVING TDAP, MCV4, MMR, VARICELLA, HEP A AND GARDASIL. GARDASIL WAS LAST VACCINE BEFORE PATIENT WENT LIMP. B/P 125/50, P 110 PO2 100% PATIENT WAS A&0X3 AFTER NOT RESPONDING FOR 15-20 SECONDS. 10:15AM B/P 110/76 P 115 PO2 100% A&OX3. DENIES DIZZINESS. STATES SHE HAS HEADACHE. ORANGE JUICE GIVEN. 10/27/09 Medical records incliuding vaccine records received for DOS 8/20/and 10/7. Final DX for 10/7: Viral Syndrome. 8/20 Routine visit for immunizations. Immediately following Last vaccine became limp, unresponsive. Eyes fluttered, body twitched x5-10 seconds. Opened eyes. Vitals stable. A&O x3. C/O HA, nausea. Tachycardia, c/o arm pain. Neg Romberg. PERLA. Ambulates w/no difficulty. Discharged to home. 10/7 ED visit for viral illness . ABX gtts for R eye. Influenza A/B test neg. Discharged to home.

Other Meds: NONE

Lab Data: NONE. LABS & DIAGS: Influenza A/B test neg.

History: CERUMEN IMPACTION. PMH: Unknown ALLERGIES: Unknown

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362179-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		22-Oct-2009	23-Oct-2009	--	WAES0910USA01317	23-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Skull fracture, Syncope

Symptom Text: Information has been received from a Physician Assistant concerning an "about 11 year" old female patient who was vaccinated with her first 0.5 ml dose of GARDASIL (Lot # was not provided). The reporter mentioned that in July 2009 the patient experienced fainting and skull fracture and was hospitalized for 2 days after her vaccination with GARDASIL. The patient sought medical attention. The patient was recovered on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **362181-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Oct-2008	02-Feb-2009	117	22-Oct-2009	23-Oct-2009	PA	WAES0910USA02024	11-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAOB747AA	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0995X	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Electric shock, Fall, Head injury, Screaming, Syncope

Symptom Text: Information has been received from a medical assistant and medical record concerning a 14 year old former healthy female with no known allergies who on 08-OCT-2008 was vaccinated intramuscularly with a third dose of GARDASIL (lot number 659964/1978U) in the left deltoid, a second dose of VARIVAX (Merck) (lot number 661661/0995X) subcutaneously in the right arm and a second dose of HAVRIX (lot number AHA0B747AA) intramuscularly in the right deltoid. On 02-FEB-2009 at 07:47 in the morning the patient experienced syncope and was transferred to the hospital emergency room. The head CT was negative and blood sugar was 97 which was normal. The patient was diagnosed with possible electrical shock. It was reported that the patient stated that she was shocked via hair straightener. The patient saw the physician on the same day and was diagnosed with possible seizure post electrical shock. On 10-APR-2009 the patient experienced seizure for 2 minutes, fell and hit her head on the floor and was sent to ER. The patient was started with TEGRETOL 200 mg twice a day. On 25-MAY-2009 dose of TEGRETOL was increased to 400 mg twice a day then 500 mg twice a day. The patient was also treated with folic acid 5 mg daily. On 04-MAY-2009 the patient experienced seizure for the third time. On 25-MAY-2009 therapy with TEGRETOL was discontinued and changed to KEPPRA. It was reported that the patient recovered on medications on 23-SEP-2009. On 29-SEP-2009 electroencephalograpy (EEG) showed abnormal for 3 electrographic seizures. Seizures were considered to be an other important medical event by the reporter. Additional information is not expected. All available medical records will be provided upon request. 01/05/10 MR received for DOS 09/17/09. DX: Grand mal seizures. Pt presented with grand mal sz lasting 5 mins and loud screem. Pt A, Ox3, comfortable; neuro exam: normal. Pt discharged home in stable condition.

Other Meds:

Lab Data: head computed axial, 02/02/09, negative; electroencephalograpy, 09/29/09, an abnormal EEG due to the presence of three electrographic seizures; blood glucose, 02/02/09, 97, normal DX studies: ECG: asymptomatic; GCS: 14; Head CT: normal.

History: PMH: seizures; Allergies: NKDA.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362198-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Oct-2009	15-Oct-2009	0	22-Oct-2009	23-Oct-2009	FR	WAES0910PHL00029	23-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Gaze palsy, Injection site pain, Muscle rigidity, Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female with convulsion who on 15-OCT-2009 was vaccinated with GARDASIL. Concomitant therapy included KEPPRA. On 15-OCT-2009 the patient experienced pain at injection site and seizure 30 seconds after the vaccination was received. The physician was convinced that it is a seizure rather than twitching associated with syncope due to stiffening of extremities and upward rolling of the eyeballs. On 15-OCT-2009, the patient recovered from seizure before leaving the physician's clinic. The physician felt that seizure was not related to therapy with GARDASIL, as it is "probably more related to the pain". Upon internal medical review, seizure was considered an important medical event. No further information is available.

Other Meds: KEPPRA

Lab Data: Unknown

History:

Prex Illness: Convulsion

Prex Vax Illns:

Vaers Id: **362317-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Aug-2007	16-Aug-2007	2	22-Oct-2009	04-Nov-2009	IA		04-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Over 70 warts developed on her arms and legs 11/3/09: Vaccine record received, VAERS updated.

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **362334-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	15-Jan-2008	15-Jun-2008	152	22-Oct-2009	27-Oct-2009	TX		10-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Left arm	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: The dates are estimated. I had never had HPV, and all of a sudden, after the shot I had it. No new sexual partners. My first thought was it was from the vaccine. 10/28/2009 records from OB-GYN. Patient with + HPV on pap smear 7/2008, patient had surgery to remove, had no other sx.

Other Meds:

Lab Data: I have all of the bad cells removed in a very painful surgical procedure. I then had a clear pap last December. Pap smear + HPV 7/2008

History: No PMH: Amenorrhea Allergies: NKDA

Prex Illness: No

Prex Vax Illns:

Vaers Id: **362350-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Oct-2009	22-Oct-2009	0	23-Oct-2009	02-Nov-2009	NV		26-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	NULL	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Fall, Joint swelling, Nervousness, Skin laceration, Swelling face, Syncope, Tremor, X-ray normal

Symptom Text: MY DAUGHTER FAINTED WITHIN 30 SECONDS AND FELL FLAT ON HER FACE FROM THE DOCTORS TABLE. STAFF BEGAN VITALS, OXYGEN, I.V... X-RAYS OF HER FACE WERE TAKEN, NOTHING BROKE BUT HER FACE AND NOSE IS SWELLED AND GASHED. HER RIGHT KNEE IS SWOLLEN AND IS CAUSES HER PAIN AS WELL. SHE IS SHAKEY. SHE WAS RELEASED AFTER A FEW HOURS OF EVALUATION AT URGENT CARE. WE WERE TOLD IT WAS BECAUSE SHE WAS ON HER PERIODAT THE TIME OF VACCINATING WITH GARDASIL. NO MEDS PERSCRIBED. WE WERE TOLD TO COME BACK IN 2 MONTHS. THIS HAPPENED TODAY. MY FATHER CONSENTED TO THIS VACCINATION BECAUSE HE IS LEGAL GUARDIAN. HE WAS TOLD SHE SHOULD GET THIS BECAUASE SHE IS SEXUALY ACTIVE. AND IT WAS SAFE.. I HAVE BEEN EDUCATING MYSELF WITH THIS GARDASIL AND I AM VERY FEARFULL THERE IS IRREVERSABLE DAMAGE DONE.... 11/16/2009, PCP/Urgent Care records from 10/22/2009, post vaccine, patient with a syncopal episode that resulted in a fall, patient striking her nose. xrays neg for fx. tx: ice pack and Motrin,

Other Meds: NONE

Lab Data: Labs: CBC, CMP, UA normal Dx studies: Xrays of nasal bones neg for fx

History: none PMH: None Allergies: NKDA

Prex Illness: none

Prex Vax Illns:

Vaers Id: **362405-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	16-Oct-2009	16-Oct-2009	0	23-Oct-2009	26-Oct-2009	--	WAES0910USA02110	26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a registered nurse concerning a 21 year old female patient who on 16-OCT-2009 was vaccinated with the first dose of GARDASIL (lot # not reported). It was reported that on 16-OCT-2009 the patient was vaccinated and experienced two seizures about 5 seconds each and approximately two minutes apart. The nurse stated that the patient had not eaten all day. The nurse indicated that the doctor came into the patient's room and held her legs up while she had the seizures. The nurse stated that the patient had some vitamin water before she left the doctor's office. Lab diagnostics studies were not performed. On 16-OCT-2009, the patient recovered. The patient walked out of the office. Seizures were considered to be an other important medical event by the registered nurse. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362406-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		23-Oct-2009	26-Oct-2009	--	WAES0910USA02114	26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Anaphylactic shock

Symptom Text: Information has been received from a consumer who received an e-mail from a friend, which received the email from his friend concerning "one of his adult daughters" who on an unspecified date received GARDASIL. It was reported that within hours the patient went into anaphylaxis shock. The patient went to the ER where she was told that she had been within 10 minutes of dying. At the time of the report the patient status was unknown. The reporter considered anaphylaxis shock to be immediately life-threatening. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **362407-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Feb-2008	27-Apr-2008	86	23-Oct-2009	26-Oct-2009	FR	WAES0910USA02182	26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Computerised tomogram normal, Cranial nerve disorder, Diplopia, Nuclear magnetic resonance imaging normal, Paresis, Scan brain, Visual acuity tests normal

Symptom Text: Information has been received from a Health Agency concerning a 14 year old female patient who received the first dose of GARDASIL (batch number not reported) via IM route at the end of February 2008 (exact date not provided). On 27-APR-2008, approximately two months after vaccination, a diplopia abruptly appeared for which she consulted. Cerebral CT scan was normal. A fluctuant monocular oblique diplopia in relation with a paresis of the right superior oblique was observed. MRI performed on 24-MAY-2008 was normal. Visual acuity was normal (10/10e). On 16-JUN-2008, diplopia was still present. Decompensation of a trochlear nerve was considered. At the time of reporting the outcome was unknown. The reporting Health Agency considered that diplopia and cranial nerve disorder NOS were medically significant as other important medical events. The Health Authority assessed the causal relationship between the reported reactions and vaccination as "doubtful" according to the method of assessment. Other business agreement numbers included: E2009-09449. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362408-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Sep-2009	17-Sep-2009	0	23-Oct-2009	26-Oct-2009	FR	WAES0910USA02193	26-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ28270	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Clonic convulsion, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a Health Authority (ref # DK-DKMA-20092923) concerning an 11 year old female patient who was vaccinated IM with the first dose of GARDASIL (batch # NK14370; lot # NJ28270; site of administration not reported) on 17-SEP-2009. Immediately after vaccination, the patient experienced clonic convulsion and syncope vasovagal. The patient recovered on the same day. The patient had no concurrent illness and received no concomitant medicine. Upon internal review clonic convulsion and syncope vasovagal were considered to be an other important medical event. Other business partner numbers include: E2009-09431. The case is closed. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362420-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Oct-2009	23-Oct-2009	0	23-Oct-2009	02-Nov-2009	DE		02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3027AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncopal episode lasting 30 seconds

Other Meds: Received PPD on 10/20/09

Lab Data: none

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362438-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	22-Sep-2009	12-Oct-2009	20	23-Oct-2009	02-Nov-2009	CA		11-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	MSD 1043Y	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	MSD 0672Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Paraesthesia

Symptom Text: Reports distal parasthesias of both hands and feet with proximal radiation. Negative physical exam 11/3/09 Medical records received for date 10/23/09. DX: distal parasthesias. Pt. c/o parasthesia on feet, both hands, numbness tingling radiates proximally x10 days. Pt. parent concerned about GBS. Pt vax on 9/22/09 HPV VZV. Assessment: distal parasthesias. Pt to be seen by specialist.

Other Meds: NO

Lab Data: Results pending 11/3/09 Medical records received for date 10/23/09. Diagnostics/Labs: CBC and Chemistry WNL, ANA 1.40(H).

History: NO

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **362439-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	23-Oct-2009	23-Oct-2009	0	23-Oct-2009	02-Nov-2009	VA		02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysgeusia

Symptom Text: Pt reported salty taste in her mouth concurrently with Gardasil injection.

Other Meds: None

Lab Data: None

History: Allergies: singulair, phenergan, fenugreek Birth defects: none Medical conditions: none

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362513-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Mar-2007	06-Oct-2009	936	23-Oct-2009	06-Nov-2009	TN		28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0637F		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Discovered high-risk HPV on pap.

Other Meds:

Lab Data: High-risk HPV on pap smear

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **362521-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Oct-2009	12-Oct-2009	2	23-Oct-2009	30-Oct-2009	WA		02-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB32	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0653X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3021AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B038CA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0973Y	1	Right arm	Subcutaneously	
FLU	SANOFI PASTEUR	U3204AA	3	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling, Injection site warmth

Symptom Text: Phone report from mother. Left arm swollen, red, hot to touch, itchy. Swollen area is full circumference of arm and extends approximately 6 inches from top of deltoid to mid upper arm. No fever. Mother giving Tylenol and topical hydrocortisone. Advised mother to contact pediatrician. Mother called back on 10/14/2009 and stated patient had seen Dr. and was given an antibiotic. Redness and swelling is resolving.

Other Meds:

Lab Data:

History: History of migraine headaches

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362702-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	05-Jun-2009	15-Jun-2009	10	25-Oct-2009	03-Nov-2009	OH		04-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Hair loss, thinning hair

Other Meds: Allegra, Albuterol, Singular, Allergy injections

Lab Data:

History: Hayfever, allergies to dogs, cats, peanuts, garlic, lemons

Prex Illness: No

Prex Vax Illns:

Vaers Id: 362772-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Sep-2009	10-Oct-2009	25	26-Oct-2009	03-Nov-2009	MI		24-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness unilateral, Cough, Immediate post-injection reaction, Pain, Photosensitivity reaction, Pyrexia, Upper respiratory tract infection, Vision blurred

Symptom Text: Loss of vision R eye; Started having photosensitivity right after the second HPV Immunization. 10/27/09: Ophthalmology records received for dates of service 10/14/09 to 10/27/09. Dx: Infiltrative Keratitis. Assessment: Presented with moderate to severe loss of vision in R eye and diagnosed with diffuse Infiltrative Keratitis. Prescribed Pred. Forte and Vigamox and instructed to d/c contact lens use. One week later, patients level of comfort was good, but vision was still blurry. Instructed to continue meds. QID. 6 days later vision remained blurry. ```MR received 01/29/10 for DOS 10/26/09. Pt c/o cough, chills, fever, and body aches. Assessment: upper respiratory infection. TX: Advil. Pt improved and discharged home.

Other Meds: None Did recieve Hep A #1, Varicella on 6/11/09 with HPV # 1.

Lab Data: Infiltrative Keratitis OD; if things don't improve may need corneal transplant. 10/27/09: Ophthalmology records received for dates of service 10/14/09 to 10/27/09. Labs and Diagnostics: None. ```Lab and DX studies: T 102,5F

History: None. 10/27/09: Ophthalmology records received for dates of service 10/14/09 to 10/27/09. PMH: Allergy to Augmentin. ```PMH: Keratitis Keratoconjuctivitis in exanthemas, barriers to learning.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **362777-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Oct-2009	21-Oct-2009	1	26-Oct-2009	05-Nov-2009	MN		05-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB327AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0864Y	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Swelling

Symptom Text: 10/20/09 - Mild erythema + swelling - Reaction occurred morning after vaccine was administered per pt. 10/21/09 - Treatment: Ice, BENADRYL ointment, RTC if symptoms persist.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Oct-2009	26-Oct-2009	4	26-Oct-2009	26-Oct-2009	FL		29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU(H1N1)	SANOFI PASTEUR	UP003AA	1	Right arm	Intramuscular	FLU
	HPV4	MERCK & CO. INC.	MSD 0671Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Chest pain, Facial palsy, Headache, Hypoaesthesia facial, Paraesthesia, Tongue paralysis

Symptom Text: Bell's Palsy per ER doctor. Given Antibiotics and steroids. 10/27/09 ED records received service date 10/25/09. Assessment: Bell's Palsy Presented with right facial droop, numbness, and tingling. Left tongue deviation. Substernal chest pain. Headache, chest heaviness, and pressure in head.

Other Meds:

Lab Data: 10/27/09 ED records received service date 10/25/09. LABS AND DIAGNOSTICS: CT Scan Brain - WNL

History: None, per mother. 10/27/09 ED records received service date 10/25/09. Asthma.

Prex Illness: None, per mother.

Prex Vax Illns:

Vaers Id: **362822-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Oct-2007	04-Feb-2008	123	23-Oct-2009	06-Nov-2009	NY		06-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Multiple sclerosis, Syncope

Symptom Text: My daughter received GARDASIL on 10/04/2007 and was diagnosed within 6 months with vasovagal syncope and Multiple Sclerosis. She was 16yrs old at her diagnosis and many doctors have commented on how young she was to be diagnosed. After researching the H1N1v vax and its possible side effects, it sparked conversations of other vaccines and side effects. I spoke with my sister who is a dr of pharm and she suggested reporting our situation to the FDA. I also did some further looking into reports of GARDASIL and MS and instances have been reported. I this this could be a valid concern.

Other Meds:

Lab Data: Diagnosed with MS from MRI.

History: No other med conditions...

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362846-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	14-Feb-2007	14-Feb-2007	0	26-Oct-2009	27-Oct-2009	FR	WAES0910MYS00003	27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Thrombosis, Vaginal haemorrhage

Symptom Text: Information has been received from a physician concerning a 28 year old female history of 2 pregnancies and 1 live birth who on 14-FEB-2007 was vaccinated with the first dose of GARDASIL. On 13-APR-2007 (2 weeks, 3 days prior to last normal menstrual period), the patient was vaccinated with the second dose of the vaccine. On 1-MAY-2007, the patient had her "last normal menstrual period". Eight weeks after LNMP, on approximately 1-JUL-2007, the patient started bleeding for days with clots- the patient had a miscarriage. Subsequently, in July 2007, the patient recovered from the miscarriage. On 21-JUL-2007, the patient experienced menstruation again (last menstrual period). Subsequently, the patient became pregnant (refer to WAES#0907MYS00009). The reporter felt that miscarriage was not related to therapy with GARDASIL. The cause of the miscarriage is not known. Upon internal review, miscarriage was considered an important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 01May07)

Prex Vax Illns:

Vaers Id: 362847-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	26-Aug-2009	14-Sep-2009	19	26-Oct-2009	27-Oct-2009	--	WAES0910USA01318	03-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Blood pressure abnormal, Computerised tomogram normal, Dyspnoea, Echocardiogram normal, Feeling of body temperature change, Myalgia, Paraesthesia, Pulse abnormal, Tachycardia, Ultrasound Doppler normal

Symptom Text: Information has been received from a consumer concerning her daughter, an 18 year old female without pertinent medical history and allergies to Cecore, amoxicillin and sulpha who was vaccinated with a dose of GARDASIL in May or June 2009 and "about 5 weeks ago" approximately on 07-SEP-2009 respectively. Concomitant therapy included YASMIN, CYMBALTA and ADDERALL. The reporter mentioned that on approximately 14-SEP-2009 "4 weeks ago" after the patient received the second dose of GARDASIL she started experiencing difficulty breathing and tingling sensations in her arms and legs. It was also reported that "about a week ago" approximately on 07-SEP-2009 the patient was hospitalized for 24 hours because her blood pressure and her pulse were erratic (pulse at 150 to 160). The reporter mentioned that her daughter was still having tingling, as well as joint and muscle pain and she does seem to able to get in a comfortable body temperature (she was either cold or really hot). The patient sought unspecified medical attention. Follow-up information was received from an office Manager who reported that the patient received on 20-MAY-2009 the first dose of GARDASIL (Lot # 661953/1130X) and on 26-AUG-2009 the second dose of GARDASIL (Lot # 661952/1129X). The reporter also mentioned that the patient did not receive any concomitant vaccinations when the GARDASIL vaccinations were administered. Additional information has been requested. 10/29/09: Emergency Department records received for date of service 10/5/09. Dx: Narrow complex tachycardia Assessment: Presents with dyspnea, described as mild. No cough, sputum production, fever or chills. No chest pain or discomfort. Tachycardic. Pleural effusion and pulmonary embolism ruled out. Admitted to hospital.

Other Meds: ADDERALL TABLETS; YASMIN; CYMBALTA

Lab Data: pulse oximetry, 150 to 160 10/29/09: Emergency Department records received for date of service 10/5/09. Labs and Diagnostics: CT: No CT evidence of pulmonary embolism. Transthroacic Echocardiogram: Normal left ventricular size and

History: 10/29/09: Emergency Department records received for date of service 10/5/09. PMH: Dyspnea previously, smoker

Prex Illness: Penicillin allergy; Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362848-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		26-Oct-2009	27-Oct-2009	--	WAES0910USA01802	27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Conversion disorder, Heart rate irregular, Migraine, Muscle spasms, Nausea, Rash erythematous, Syncope, Tremor, Weight decreased

Symptom Text: It was reported in a newspaper article that an 18 year old formerly healthy female who on an unspecified date was vaccinated with a second dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient experienced migraine-type headache fainting episode after the first two shots but did not consider it as possible side effect. On an unknown date, the patient was vaccinated with a third dose of GARDASIL (lot number, injection site and route not reported). The patient experienced CHARLEY-HORSE-type pain in her right leg led to spasms and tremors, an irregular heartbeat and nausea so severe that she lost 15 pounds in one month and had to go on intravenous fluids. The patient also developed a red rash on her upper body around the same time. The patient went to see the physician, and the physician told her that she had a "conversion disorder", in which stress caused physiological symptoms. The patient reported that her ailments had been getting worse for months, ever since she got her third GARDASIL shot. The patient felt that her adverse events were related to therapy with GARDASIL but most of her physician did not consider GARDASIL a possible cause. The patient though that fainting episode eventually disabled her. The patient reported that " I have not walked in six months". This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **362849-1** **Related reports:** 362849-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		26-Oct-2009	27-Oct-2009	--	WAES0910USA02373	27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Chronic fatigue syndrome, Dyspepsia, Hypoaesthesia, Muscle spasms, Myalgia, Nausea, Pain, Paralysis, Rash

Symptom Text: It was reported in a newspaper article that a 17 year old female who on 09 February (year unknown) was vaccinated with a dose of GARDASIL (lot number, injection site and route not reported) and a dose of MENACTRA. Subsequently the patient experienced digestive problems, rashes, severe muscle pain. The patient's mother reported that the patient was in pain every day. The patient had to drop out of a major skating competition because she can no longer land jumps or handle a four-minute routine. The patient was seen by several physicians. The patient agreed that something catastrophic must have happened to cause the extreme nausea that put the patient on acid blockers, the muscle pain that at one time required morphine, and that "roaming paralysis" that sometimes cramped her hands into claws and numbed her feet. Finally, in April, a rheumatologist wrote that the patient most likely was suffering from positive fatigue syndrome. Without explaining, the rheumatologist wrote that "it was possible" but "not very likely" that the patient's Feb, 9 GARDASIL and MENACTRA immunizations triggered the symptoms. The patient's mother was convinced that GARDASIL caused her daughter's symptoms. Upon internal review, paralysis was determined to be an other important medical event. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **362849-2** **Related reports:** 362849-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		06-Nov-2009	09-Nov-2009	--	200904502	13-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Chronic fatigue syndrome, Dyspepsia, Hypoaesthesia, Muscle spasms, Myalgia, Nausea, Pain, Paralysis, Rash

Symptom Text: Initial report received on 27 October 2009 from another manufacturer (report number WAES 0910USA02373). The other manufacturer had obtained via a newspaper article. The following is verbatim from their report. "It was reported in a newspaper article that a 17 year old female who on 09, February (year unknown) was vaccinated with a dose of GARDASIL (lot number, injection site and route not reported) and a dose of MENACTRA. Subsequently the patient experienced digestive problems, rashes, severe muscle pain. The patient's mother reported that the patient was in pain every day. The patient had to drop out of a major skating competition because she can no longer land jumps or handle a four-minute routine. The patient was seen by several physicians. The patient agreed that something catastrophic must have happened to cause the extreme nausea that put the patient on acid blockers, the muscle pain that at one time required morphine, and the "roaming paralysis" that sometimes cramped her hands into claws and numbed her feet. Finally, in April, a rheumatologist wrote that the patient most likely was suffering from positive fatigue syndrome. Without explaining, the rheumatologist wrote that "it was possible" but no very likely" that the patient's Feb, 9 GARDASIL and MENACTRA immunizations triggered the symptoms. The patient's mother was convinced that GARDASIL caused her daughter's symptoms. Upon internal review, paralysis was determined to be other important medical event. This is one of several reports from the same source. No further information is available." It is noted that other cases in the article were not reported as having received MENACTRA. Documents held by sender: None.

Other Meds:

Lab Data: Not reported

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **362850-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	01-Sep-2009		26-Oct-2009	27-Oct-2009	--	WAES0910USA02410	12-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Pulmonary embolism, Thrombosis

Symptom Text: Information has been received from a nurse concerning an 18 year old female patient who on unspecified dates was vaccinated with the first and second dose of GARDASIL (lot number not reported). On 19-OCT-2009 the patient was in the office for the third dose of GARDASIL (lot number not reported). The patient was currently on long term COUMADIN therapy after a blood clot in her lungs 3 weeks ago (September 2009). The patient's COUMADIN levels were stable. Unspecified medical attention was sought. At the time of the report, the outcome of the patient was not reported. Upon internal review, blood clot in lungs was determined to be an other important medical event. Additional information has been requested. ```MR and DC summary received 02/08/10 and 02/12/10 for DOS 09/23/09. Pt c/o frequent episodes of SOB in exertion and rest time. Tx: Clarythromycin. On examination: sinus tachycardia and CXR confirmed bilateral PE. Pt recently had a long plane ride. Tx: lovenox. DX: pulmonary embolism\infarction.

Other Meds: Unknown

Lab Data: ```Labs and DX studies: CXR confirmed PE, HR 114 bpm. PT 13.1 (H), INR 1.11

History: ```PMH: use of OCPs. Allergies: none.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **362851-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-May-2008	Unknown		26-Oct-2009	27-Oct-2009	FR	WAES0910USA02471	27-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1049U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epilepsy, Vaccine positive rechallenge

Symptom Text: Information has been received by a gynecologist concerning a 15 year old female with a medical history of DOWN's syndrome who was vaccinated with a first dose of GARDASIL (Batch # NG46500, Lot # 1049U) intramuscularly on 14-MAY-2008, injection site not reported. About 2-3 days post vaccination the patient experienced an epileptic seizure for the first time. On 16-JUL-2008 the patient received a second dose of GARDASIL (Batch # NH16170, Lot # 1477U) intramuscularly, injection site not reported. About one week post vaccination the patient developed a second epileptic seizure. After the third dose of GARDASIL (Batch # NH17960, Lot # 1427U) intramuscularly, injection site not reported on 21-APR-2009 the patient developed series of epileptic seizures. Diagnosis of epilepsy was established. She was treated with anticonvulsives but continued to have epileptic seizures. Epilepsy was considered an other important medical event. Other business partner numbers include E2009-09495. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Down's syndrome

Prex Vax Illns:

Vaers Id: **362859-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	U	15-Oct-2009	15-Oct-2009	0	26-Oct-2009	05-Nov-2009	CO		28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0968Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Disorientation, Disturbance in attention, Dizziness, Hypoaesthesia

Symptom Text: Disoriented, numbness in body, lack of concentration, dizzy, high anxiety.

Other Meds:

Lab Data: Blood work-up & MRI

History: None

Prex Illness: None

Prex Vax Illns: 08-13-09~HPV (Gardasil)~1~20.00~Patient

Vaers Id: **362933-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Mar-2007	18-Mar-2007	6	27-Oct-2009	03-Nov-2009	AZ		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB242BA		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	176SU		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	17406	1	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Depressed level of consciousness, Fatigue, Lethargy, Muscular weakness

Symptom Text: Extreme Fatigue. Lethargic reaction. Extreme Weakness in joints and muscles. Almost non responsive. Emergency room visit resulting in IV, antibiotic injections and short stay in hospital.

Other Meds:

Lab Data: Blood Work Up, Strep Test.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **363027-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	21-Oct-2009	24-Oct-2009	3	27-Oct-2009	03-Nov-2009	MN		03-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site haematoma, Injection site papule, Injection site rash, Injection site urticaria

Symptom Text: Pt developed a large bruise at injection site and then proceded to develop a gradual onset of hives, small raised and pink and additionally developed a fine sandpaper rash.

Other Meds:

Lab Data: Evaluation by a Nurse Practitioner

History: Pt has a sulfa allergy

Prex Illness: None reported

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **363103-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Sep-2009	16-Sep-2009	15	27-Oct-2009	28-Oct-2009	FR	WAES0910USA02621	28-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cardiac stress test, Dizziness, Nausea, Syncope, Weight decreased

Symptom Text: Case received from a health care professional on 16-OCT-2009. This case is poorly documented. It was reported by a gynaecologist that 15-year old female patient was vaccinated with an unspecified dose of with GARDASIL (lot #, injection route and site not reported) on 01-SEP-2009. On 16-SEP-2009, during physical education, the patient fainted. Additionally she developed nausea, dizziness and weight loss on an unspecified date. She was admitted to hospital for investigation. Stress ECG (electrocardiogram) was discontinued for unspecified reason. At the time of reporting the patient was in internistic therapy. Duration and outcome were not yet reported. Other business partner's numbers included: E2009-09613.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **363144-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Oct-2009	19-Oct-2009	0	27-Oct-2009	09-Nov-2009	AZ		11-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3827CA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	U2937BA	5	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Nausea

Symptom Text: C/O nausea & chest discomfort. B/P 96/68.

Other Meds: None

Lab Data: None

History: None

Prex Illness: Physical

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **363162-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Nov-2007	01-Dec-2007	11	27-Oct-2009	06-Nov-2009	NH		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	09304	1	Left arm	Intramuscular	HPV4
	FLU	SANOFI PASTEUR	U2524AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dermatomyositis, Rash

Symptom Text: Dermatomyositis - Dx'd 2/2008. 1st Dx'd by rash on knuckles found during DERM visit for acne on 2/7/08. Pt & mother stated rash had been present for few months. Rx'd with PLAQUENIL.

Other Meds: ALBUTEROL PRN

Lab Data: CBC; LPT'S; CPK; ANA; ENA; Skin biopsy (c/w connect. Tissue disease); ANA Positive; All other labs - Negative/NL

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **363226-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	26-Oct-2009	26-Oct-2009	0	27-Oct-2009	07-Nov-2009	WI		09-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0968Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Syncope

Symptom Text: C/o nausea; syncope observed patient for 20 minutes after syncope, provided water

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **363230-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	31-Jul-2009	29-Aug-2009	29	27-Oct-2009	02-Nov-2009	KS		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Dizziness postural, Dyspnoea, Fatigue, Headache, Hyperreflexia, Hypoaesthesia, Photophobia

Symptom Text: chest pain, difficulty breathing, headache, extreme fatigue, ```1/27/10 PCP records rec'd for WCC 7/31/09. Assessment: healthy with scoliosis-L thoracic curve. HPV vax given. ```2/1/10 MR rec'd for DOS 9/28-10/1/09 with dx: Headache, intractable and severe in nature. Pt presented with ~1 month hx of H/A and pressure which began 8/27/09, 5-9/10 intensity. Some SOB and chest pain in the beginning and occ. (+) photophobia. Slight numbness R toe. Dizziness upon standing. DTRs brisk otherwise neuro exam WNL. Started on Depakote and dihydroergotamine with little improvement. D/C to f/u as outpt.

Other Meds:

Lab Data: echocardiagram,chest x-ray(2), MRI of the brain, spinal tap, eye exam(2),blood work, strep cultures, mono test, etc.,etc., ```Labs and diagnostics: Echo WNL. MRI brain (+) small pituitary cysts. Labs WNL.

History: ```PMH: Malrotated pancreas repair. Appy. Hernia repair. Dehydration. Scoliosis. ```2/4, 2/10 & 2/12/10 Hospital records and discharge summary received for dates of service 9/28/09 to 10/1/09. PMH: Born at 33 weeks EGA, overweight.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **363258-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Oct-2009	24-Oct-2009	1	27-Oct-2009	30-Oct-2009	WA		30-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037AA	0	Left arm	Intramuscular	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	98435P1	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0594Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1311X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Injection site erythema, Injection site nodule, Injection site warmth, Nausea, Pain in extremity, Tremor, Vomiting

Symptom Text: Pt had left arm pain. Varicella SQ site was hot to touch w/ red, hot knot approx. 2-3" in diameter. Redness of arm from elbow up to 2" above site. Had shakes, no fever and did not feel cold, stomach pain - nausea, vomiting. No diarrhea. As of 10/27/09, pt feeling better, able to eat and drink. Still has red arm and knot at varicella vaccine site.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **363343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	17-Jul-2009	17-Jul-2009	0	28-Oct-2009	29-Oct-2009	TX	WAES0908USA02961	29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer for the Pregnancy Registry for GARDASIL, concerning a 25 year old female with no drug reactions/drug allergies reported and no pertinent medical history, who on 17-JUL-2009 was vaccinated IM with 0.5 ml first dose GARDASIL (lot number not reported). Concomitant therapy included Omeprazole. The patient stated she came pregnant after getting her first dose of GARDASIL, she was " 1 month or 5 weeks pregnant". When asked she verified that she was not pregnant at the time of vaccination. The patient did not have any regular doctor. No laboratory tests were performed. No adverse event reported. The patient sought unspecified medical attention. Follow up information has been received from a consumer who stated that she received one injection, she lost the baby and she was pregnant again (WAES 0910USA03215). At the time of this report the patient's outcome was unknown. Upon internal review, to lose a baby/abortion was determined to be an other important medical event. Additional information has been requested.

Other Meds: omeprazole

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 363345-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Oct-2009	15-Oct-2009	0	28-Oct-2009	29-Oct-2009	TN	WAES0910USA02800	29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	500723P		Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Urinary incontinence

Symptom Text: Information has been received from a physician concerning a 13 year old female patient without a pertinent medical history or drug reactions/allergies who on 15-OCT-2009 was intramuscularly vaccinated her first 0.5 ml dose of GARDASIL (Lot # 661703/0651X). Secondary suspect vaccine included FLUMIST (Lot # 500723P). The reporter mentioned that a Nurse first administered on 15-OCT-2009 FLUMIST and when they were giving the patient GARDASIL, the patient passed out and had what they described a seizure. It was reported that the patient urinated on herself. According to the physician the patient was admitted into hospital and she was observed for 24 hours and then discharged. Also was reported that the patient was diagnosed with seizures. The Nurse at the Doctor's office did not believe the adverse experience was caused by GARDASIL. No laboratory or test diagnostics were performed. The patient recovered after stopping therapy on an unspecified date. As a final statement the physician mentioned that the patient had "one episode like that previously within the last couple of years while at school" and the patient was not being given any medications or vaccination when that happened previously. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 363350-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	15-May-2009	15-May-2009	0	28-Oct-2009	29-Oct-2009	FR	WAES0909USA00830	14-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Hypoaesthesia

Symptom Text: Information has been received from a physician via CSL as part of a business agreement (manufacturer control number 20090907JV2) concerning a 25 year old patient who on 15-MAY-2009 was vaccinated with the first dose of GARDASIL (lot number not reported). On 16-MAY-2009 the patient developed headache and left side numbness without weakness. The patient's vision was normal. The patient was transferred to a hospital Emergency Department. Head computed axial tomography (CT) was performed and the result was normal. Magnetic resonance imaging (MRI) was performed and the result was normal. The patient was diagnosed with questionable migraine. It was noted that the symptoms lasted for a few hours and got better on its own. The patient was discharged home. The patient was not given the second dose of GARDASIL. Follow-up information has been received from the physician concerning the 25 year old female patient. On 15-MAY-2009 (previously reported as 16-MAY-2009) the patient developed headache, numbness on the left side and was hospitalised. On 16-MAY-2009 Head CT and MRI were performed and nothing abnormal detected. On an unspecified date, the patient recovered. No further information is available.

Other Meds: Unknown

Lab Data: ophthalmological exam, 16May09, vision normal; head computed axial tomography, 16May09, normal; magnetic resonance imaging, 16May09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **363352-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-May-2008	01-May-2008	0	28-Oct-2009	29-Oct-2009	OH	WAES0910USA02801	29-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a Licensed Practical Nurse for GARDASIL, a Pregnancy Registry product, concerning a 21 year old female patient who in May 2008, was vaccinated with the second dose of GARDASIL (dose, route and lot # unspecified). The nurse reported that the patient stated she became pregnant after receiving her second dose of GARDASIL and then had a miscarriage. The patient sought medical attention (office visit). Upon internal review miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **363358-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		28-Oct-2009	29-Oct-2009	RI	WAES0910USA02713	02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amyotrophic lateral sclerosis

Symptom Text: Information has been received from a physician who reported that a report was posted about two patients who developed amyotrophic lateral sclerosis 4 months after receiving their second dose of GARDASIL. At the time of the report, the patient's status was unknown. Attempts are being made to verify the existence of an identifiable patient and reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **363372-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	23-Sep-2009	23-Sep-2009	0	28-Oct-2009	04-Nov-2009	MO		01-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: After shot given 9/23/09 had increased headache. Saw her PMD, was given TYLENOL with CODEINE to relieve. He stated no more GARDASIL.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **363389-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Oct-2007	19-Oct-2007	0	28-Oct-2009	10-Nov-2009	PA		08-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U3201AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Disorientation, Dyskinesia, Fall, Loss of consciousness, Pain in jaw, Skin laceration

Symptom Text: 5:08pm on 10/19/09. Pt given GARDASIL 0.5 CC IM in L. arm & Influenza vaccine 0.5 cc IM in R. arm. After vaccine - pt alert & sitting on table. Seconds later pt fell on floor face down. I observed jerking movement of arms & legs approx 5 - 10 seconds. Pt lacerated chin - pressure & band aid applied. Vital sign stable. Pt loss consciousness only approx 2 minutes then appeared dazed. Dr. helped get patient back on table. Observed for 20 minutes. Pt fully alert after approx 3-4 minutes after incident. Patient drank cola & talked appropriately. Pt c/o discomfort in jaw area- ice applied to left side of jaw. Patient taken to ER in wheelchair - along with parents.

Other Meds:

Lab Data: X-Ray of jaw (mandible) - no fracture; X-RAY of nasal bones & maxillary spine - normal

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **363397-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Feb-2009	Unknown		28-Oct-2009	04-Nov-2009	TX	TX090011PU	20-Jan-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0651X	2	Right arm	Intramuscular	
MEN	UNKNOWN MANUFACTURER	U2816AA	0	Left arm	Intramuscular	
HEPA	UNKNOWN MANUFACTURER	AHAVB260AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: TODAY PATIENT'S MOTHER INFORMED ME THAT KAILEY (PATIENT) HAS DISCOVERED THAT SHE IS PREGNANT. SHE THINKS HER LAST MENSTRAL PERIOD WAS IN DECEMBER 2008.

Other Meds: UNKNOWN

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **363454-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Oct-2009	28-Oct-2009	0	28-Oct-2009	04-Nov-2009	NM		04-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0650X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3015AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB312AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Received Hepatitis A, Menactra and Gardasil. Fainted immediately after receiving Gardasil. Regained consciousness promptly; given first aid per protocol; monitored until fully stable; parent notified.

Other Meds:

Lab Data:

History: None; Hx cleft lip

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **363456-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Oct-2009	21-Oct-2009	0	28-Oct-2009	09-Nov-2009	NC		09-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Hypoaesthesia, Injected limb mobility decreased, Paraesthesia

Symptom Text: Shot @ around 9am L arm, @ 10:45am, tingling sensation from shoulder to fingers, then decreased strength then numb unable to use. L leg tingles. @ 2:45, numbness resolves, tingling starts @ 4:00pm - painful L humenous forarm . still present x 4 - 6 hours then resolved.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 363546-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Aug-2009	19-Aug-2009	1	29-Oct-2009	30-Oct-2009	CA	WAES0909USA00379	11-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Disturbance in attention, Dizziness, Fatigue, Headache, Vaccination complication

Symptom Text: Information has been received from a physician concerning a female patient who on approximately 12-AUG-2009, "three weeks ago", was vaccinated intramuscularly into the deltoid with a dose of GARDASIL. The next morning after vaccination, on approximately 13-AUG-2009, the patient had experienced headaches and dizziness every day for the last three weeks. The patient also had not been able to concentrate in school. The patient sought medical attention by an office visit. The patient recovered from all symptoms on 02-SEP-2009. Follow up information was received from the physician who reported that the 14 year old patient on 18-AUG-2009 was vaccinated with her first dose of GARDASIL (Lot No. 663452/0671Y). On 19-AUG-2009, the patient experienced severe headache and dizziness. The patient was prescribed ANTIVERT for the treatment of dizziness. Although the patient was going to school, she was very tired and had difficulty concentrating. The patient sought unspecified medical attention. At the time of the report, the patient had recovered from all symptoms. The patient's headache, dizziness, disturbance in attention, and fatigue were considered to be other important medical events by the reporter. No further information is available. 11/2/09 Medical records received for date 9/2/09. DX: Adverse rx to vaccine. Presenting SX: c/o severe HA, dizziness x3wks. Pt states began after first vax of gardasil.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **363548-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	05-Oct-2009	05-Oct-2009	0	29-Oct-2009	30-Oct-2009	MS	WAES0910USA03033	30-Oct-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain, Injection site swelling, Injection site warmth, Pain, Sleep disorder

Symptom Text: Information has been received from a physician concerning a 25 year old female patient, with no allergies who on 05-OCT-2009 was vaccinated a 0.5 mL dose of with GARDASIL, intramuscular route (lot # unknown). Concomitant therapy included ORTHO TRI-CYCLEN. On 05-OCT-2009 the patient noticed tenderness in her shoulder after GARDASIL had been administered in her left deltoid. She experienced severe pain for 2 days, then persistent pain to the present day. The physician reported that there was a tender, hot, swollen area 3 cm at injection site where the pain extended to her shoulder begins. The physician considered it a mild or partial disability because the patient found difficult even to raise arm to put on a T-shirt and she was having problems sleeping. The patient has been treated with an unspecified anti inflammatory with no relief, she was just started on CIPRO and LORTAB and directed to apply heat. The patient sought medical attention at the physician's office. At the time of this report the patient's outcome was unknown. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **363715-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	02-Jun-2009	03-Jun-2009	1	29-Oct-2009	04-Nov-2009	TX	TX090020PU	20-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	AHAVB29BA	1	Left arm	Intramuscular	
	DTAP	SANOFI PASTEUR	C308BA	4	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Injection site warmth, Pyrexia

Symptom Text: RIGHT ARM SWOLLEN, TENDER AND HOT TO TOUCH. PATIENT ALSO RAN FEVER.

Other Meds: NONE

Lab Data: CBC

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **363747-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jun-2009	01-Jun-2009	0	29-Oct-2009	04-Nov-2009	TX	TX090023PU	20-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2875AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3097AA	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0471Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event

Symptom Text: RECEIVED DTAP. MCV4, VARICELLA AND HPV ON 6/1/09 WITH NEGATIVE PREGNANCY TEST. HAS HAD NO ADVERSE EFFECTS. PT NOW HAS A POSITIVE PREGNANCY TEST.

Other Meds: BACTRIM DS

Lab Data: NONE

History: AT VISIT DIAGNOSED WITH UTI AND DEPRESSION

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: 363769-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Jul-2009	29-Jul-2009	1	29-Oct-2009	04-Nov-2009	NE		17-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0725Y	1	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0313Y	0	Left arm	Unknown	
MNQ	SANOFI PASTEUR	U2915AA	0	Left arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B046AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Cough, Decreased appetite, Dysphagia, Fatigue, Headache, Hypoaesthesia, Muscular weakness, Musculoskeletal stiffness, Nausea, Oropharyngeal pain, Pain, Paraesthesia, Pyrexia, Skin exfoliation, Viral infection, Viral pharyngitis, Vomiting

Symptom Text: Madi started getting severe stomach pains approx. 24 hours after Gardasil vaccine. She threw-up violently at least 13 times. For the next 3 weeks she suffered from fatigue, joint pain, numbness and tingling in her fingertips, fevers, nausea, sore throat, skin peeling off of her hands, muscle weakness in her legs. 11/30/09: Infectious disease consultation received for date of service 8/05/09. Dx: Viral syndrome. Presents with c/o sore throat, fever, emesis, joint pain and tingling and stiffness of fingers following vaccination. MD states sx. unlikely related to vaccine, rec. continue HPV series. 12/23/09 clinic records and laboratory reports received for DOS 07/28/09-07/29/09. DX: Acute Viral Pharyngitis. Patient presented with c/o sore throat, dysphagia and vomiting. 12/23/09 clinic records received for DOS 08/04/09-10/05/09. DX: Viral infection and acute pharyngitis. Presents with c/o headaches, fever, vomiting, joint pain, body aches, sore throat, cough and decreased appetite. Plan: Ibuprofen, fluids and rest.

Other Meds:

Lab Data: Full blood work up at Children's Hospital in Omaha, NE. Also tested for H1N1, strep, seasonal flu, meningitis. Went to Infectious Disease as well. 11/30/09: Infectious disease consultation received for date of service 8/05/09. Labs and di

History: 12/23/09 PMH: Pneumonia, Corneal abrasion, scoliosis.

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **363878-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	05-Mar-2009	13-Mar-2009	8	30-Oct-2009	02-Nov-2009	FR	WAES0910USA02987	02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1864U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Type 1 diabetes mellitus

Symptom Text: Information has been received from Health Authority (case# 104830) through a foreign agency (local case# IT431/09) concerning a 12 year old female patient with no medical history who on 05-MAR-2009 was vaccinated with the first dose of GARDASIL (lot# 1864U, batch# NJ16970) intramuscularly. On 13-MAR-2009 the patient experienced type 1 diabetes mellitus and was hospitalized. The elevated value of the glycosilate hemoglobin (13.1) indicated that the disease had been active since a few months. The patient had not yet recovered. The case is closed. Other business partner number included: E200909862. Additional information has been requested.

Other Meds: Unknown

Lab Data: whole blood glycosylated hemoglobin, elevated value (13.1)

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **363887-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	13-Oct-2009	14-Oct-2009	1	30-Oct-2009	02-Nov-2009	FR	WAES0910USA03062	02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1535U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Facial palsy, No reaction on previous exposure to drug, Sensory loss

Symptom Text: Case received from a general practitioner on 16-OCT-2009: On 13-OCT-2009 in the evening, a 21 year old female patient had received the third dose of GARDASIL vaccine (batch # NH42160, lot # 1535U). On 14-OCT-2009 in the morning, she developed sensitivity disorder on the left hemicorpus. She found it difficult to whistle and she had the feeling that her smile was not normal. On 15-OCT-2009 everything was normal. On 16-OCT-2009 in the morning, there was a recurrence with a stronger sensation. She experienced facial paralysis with sensitivity disorder at the level of the left shoulder. An MRI was performed which showed a post-vaccinal acute disseminated encephalomyelitis. The patient was hospitalized to have neurological examination and lumbar punction. There was no associated sign. In particular, there was no mental deterioration, nor behaviour disorder. The patient was concomitantly taking a contraceptive pill. The first and second doses of GARDASIL vaccine had been well tolerated. Furthermore, she had also well tolerated her childhood vaccinations and hepatitis B vaccine that she had received in 2006. To be noted that her sister had experienced Kawasaki's disease during her childhood. It's noteworthy that the reporter doubted that the event was linked to the vaccine. At the time of reporting, the outcome was not provided. Other business partner numbers included: E2009-09686.

Other Meds: Hormonal contraceptives (unspecified)

Lab Data: magnetic resonance imaging, 16?Oct09, a post-vaccinal acute disseminated encephalomyelitis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **363894-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		30-Oct-2009	02-Nov-2009	FR	WAES0910USA03344	02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Idiopathic thrombocytopenic purpura

Symptom Text: Case received from a health care professional on 22-OCT-2009. Information has been received from a nurse concerning her adolescent daughter with no other relevant medical history who on an unspecified date was vaccinated with the first dose of GARDASIL (lot#, route and site of administration not reported). Unspecified time post vaccination laboratory values (not specified) showed thrombocytopenia (reported term: "slight signs of ITP"). After the second dose of GARDASIL (lot#, route, date and site of administration not reported) symptoms aggravated. Diagnosis of idiopathic thrombocytopenia was established. The patient was hospitalized. At the time of this report, the patient's outcome was unknown. The reporter felt that idiopathic thrombocytopenia and condition aggravated were related to GARDASIL. Other business partner numbers include: E2009-09932. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, thrombocytopenia

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **363898-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
30.0	F	Unknown	Unknown		30-Oct-2009	02-Nov-2009	FR	WAES0910MEX00010	02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Inappropriate schedule of drug administration

Symptom Text: Information has been received from an company representative concerning a 30 year old female who in approximately 2009 was vaccinated with GARDASIL, 1st dose. The reporter stated that the physician referred the patient experienced seizures (more details not reported) after the vaccine administration. The causality and outcome were not reported. Upon internal review it was considered seizures as other medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **363899-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		30-Oct-2009	02-Nov-2009	FR	WAES0910USA02766	02-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Epilepsy, Human bite, Intentional self-injury

Symptom Text: Information has been received from a consumer concerning his adolescent daughter who was vaccinated with the third dose of GARDASIL (lot #, injection site and route not reported) on an unspecified date in 2008. 4 weeks post vaccination the patient experienced epileptiform fits and was hospitalized. Additional she developed anxiety, scratched and had bitten herself. She was treated in a youth psychiatry for 3 months. At the time of reporting the patient was sedated, but not recovered. Dose 1 and dose 2 of GARDASIL were given on unknown dates, toleration was not reported. Other business partner numbers include: E2009-09696. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364100-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Oct-2009	28-Oct-2009	0	30-Oct-2009	04-Nov-2009	AL		04-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB287AB	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Dyskinesia, Fall, Feeling hot, Immediate post-injection reaction, Nausea, Nervousness, Pallor

Symptom Text: Immediately follow administration of 2nd vaccine(Hep A) child slumped forward with jerking motions of upper and lower extremeties for 3-5 seconds. Child then lifted head up with PHN asking child name and place. Child answered appropriately. She was pale, c/o being hot and feeling nauseated. PHN lay child on bed, applied cool cloth and fanned. Called Dr. Hensleigh's office and child carried to MD for evaluation. Child and child's mother returned to Clinic approximately 30 to 45 minutes later stating that Dr. Hensleigh evaluated and determined that this occurred due to child was very nervous and apprehensive before injections. No other problems occurred and child went to school the following day, 10/29/2009. PHN called to check on child again on 10/30/2009 with mother stating child having no further problems after leaving clinic the day vaccines given, 10/28/09.

Other Meds:

Lab Data: MD visit for evaluation.

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **364124-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	24-Oct-2009	24-Oct-2009	0	30-Oct-2009	09-Nov-2009	HI		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	960306P	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0672Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Pt received his sister HPV. 0.3 ML. He was to get the flu - no adverse reactions at time of immuz.

Other Meds: None

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: 364162-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	30-Oct-2009	30-Oct-2009	0	31-Oct-2009	04-Nov-2009	MD		11-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Intramuscular	FLUN

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Adverse drug reaction, Asthenia, Chills, Diarrhoea, Fatigue, Fluid replacement, Hot flush, Nausea, Syncope, Vomiting

Symptom Text: Tightness in abdomen, violent vomiting, diarreha, fainting, weakness, fatigue 11/03/09 Vaccine record received. 11/05/09 Medical records received for DOS 10/30/09. Patient developed nausea, diar and vomiting several hours s/p vaccine. Hot and cold flashes. ED visit. All bld wrk WNL. Fluid replacement and antiemetics. Felt better. D/c to home.

Other Meds: Nuva Ring

Lab Data: Labs and Diags: WBC, BMP and UA WNL.

History: None. Allergies: None.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **364249-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Oct-2009	19-Oct-2009	0	30-Oct-2009	10-Nov-2009	AL		10-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB343BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Pallor

Symptom Text: Pt was given Hep H #2 immunization an then got HPV #2 vaccine. At that point she became limp& pale. the nurse laid her down & called for her. She was doing fine when I checked into the room. The nurse said " it appeared she had a mini seizure that lasted approx 10-15 seconds. No treatment need. Sx showed spontaneously.

Other Meds: Albuterole HFA- Phenergan; Singular-Delsym-Nasal; Advair Diskus-Lohist D

Lab Data: None

History: NKDA-Asthma without exacerbation

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364268-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Oct-2009	01-Nov-2009	2	02-Nov-2009	04-Nov-2009	CA		04-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3053AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Erythema, Pruritus, Tenderness

Symptom Text: BURNING AND ITCHY SENSATION, 3X3 INCH DIAMETER REDNESSSLIGHTLY TENDER TX-APPLY COLD COMPRESS

Other Meds: NO

Lab Data:

History: NO

Prex Illness: NO

Prex Vax Illns:

Vaers Id: 364286-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
7.0	F	09-Mar-2007	15-May-2009	798	02-Nov-2009	04-Nov-2009	MO		08-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0013U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Confusional state, Conversion disorder, Dizziness, Headache, Loss of consciousness, Nausea, Palpitations, Posturing, Syncope

Symptom Text: Child completed HPV/Gardasil series as follows 3/9/07;05/16/07;08/21/08 As of 5/2009 reported epsodes of syncope. Symptoms reported with episodes were acute confusion with loss of consciousness lasting between 30 to 60 minutes. Child reports episodes when she feels anxious or anxiety. 11/5/2009 and 11/9/2009 ED records for 5/26/2009 and Cardio/Neuro consult notes from 6/15 and 6/17/2009. Patient with c/o's syncope, mental confusion and loss of consciousness. Cardio evaluation norm, Neuro evaluation norm. DC DX Syncope Vasovagal Tx'd with Florinef 11/9/09: Neurology Consultation received for dates of service 6/17/09 to 10/28/09: Dx: Pseudoseizures. Assessment: Presents with episodes of syncope following hyperventilation, followed by periods of unconsciousness of 30 to 60 minutes during which she is unresponsive to painful stimuli. A recovery period of 20 to 30 minutes has been marked by extensor posturing of her legs and confusion as she becomes more responsive. 11/17 and 11/18 Medical records and ICD9 codes received. DOS 11/3-11/4. Final DX: Pseudoseizures w/anxiety component, altered mental status C/O of syncopal episode. Dizzy, HA, palpitations, nausea. LOC. Also cardiac consult 10/8/09. Not neurally-mediated syncope. Non cardiac. Concerns for conversion reaction. ICD9 codes: 7880.970.39, 780.4, 7

Other Meds: HPV #2 05/16/2007 HPV #3 08/21/2008

Lab Data: Patient has seen pediatric neurologist and pediatric cardiologist. They have conducted the following: EKG, sleep deprived EEG, brain MRI, and ECG - all were normal Lab studies no results noted Dx studies: Echo normal, Holter monitor, EKG

History: PMH: Migraines Allergies: NKDA 11/9/09: Neurology Consultation received for dates of service 6/17/09 to 10/28/09: PMH: as abovePMH: GERD as infant, pneumonia, frequent OM, PE tubes, migraines, arm numbness Allergies: none

Prex Illness: Patient in office for headache evaluation when she was vaccinated for first HPV

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364303-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Jun-2008	01-Aug-2009	426	02-Nov-2009	03-Nov-2009	PA	WAES0910USA03078	03-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse, for GARDASIL, a Pregnancy Registry product, concerning a 23 year old female patient who in June 2008, was vaccinated with the first dose of GARDASIL (lot#, route and site of administration not reported) and she was not given any other doses of GARDASIL because she was pregnant. Unspecified medical attention was sought. In August 2009, the patient delivered a healthy baby via C-section. Upon internal review, delivered a baby via C-section was determined to be an other important medical event. No further information is available since the office nurse reported that they did not deliver the patient's baby.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Sep-2009	23-Sep-2009	0	02-Nov-2009	10-Nov-2009	VA		10-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	1	Right arm	Intramuscular	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	97838PI	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Dizziness, Nausea

Symptom Text: 10 minutes after vaccine administration, patient experienced nausea, dizziness and abdominal discomfort.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **364355-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	02-Feb-2008	Unknown		02-Nov-2009	03-Nov-2009	--	WAES0910USA02836	13-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	3	Right arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Bedridden, Convulsion, Dizziness, Dyspnoea, Migraine, Musculoskeletal stiffness, No reaction on previous exposure to drug, Paralysis, Paresis, Syncope, Tunnel vision

Symptom Text: Information has been received from a consumer concerning her 28 year old female niece with no pertinent medical history and no drug reactions or allergies who in May 2008 was vaccinated with the first dose of GARDASIL. The patient had no adverse experience after first vaccination. On an unspecified date, the patient was vaccinated with the second dose of GARDASIL. There was no concomitant medication. Subsequently, within a week after the patient received the second dose of GARDASIL, the patient experienced tunnel vision, migraine headaches, shortness of breath, paralyzation. The patient couldn't move her right arm. Her right leg was now getting stiffed. The patient had seizure after two weeks of receiving the second dose of GARDASIL and she had been having seizures periodically since then. The patient was hospitalized twice (Hospital demographics and number of days of hospitalization were unspecified), once in 2008 and another in 2009. The patient was currently at home and she was bedridden. Therapy with GARDASIL was discontinued. At the time of the report, the patient had not recovered. Additional information has been requested. 12/29/2009 PCP records for 6/2008 to 11/2009. Patient with c/o's rt arm paresis, seizure activity, dizziness, syncope, headaches, ? etiology, has had multiple ED visits for these c/o's, unable to work since 4/2008, lack of insurance has prevented appropriate consults and further testing 12/29/2009 labs and dx studies dating from 6/2008 to 11/2009

Other Meds: None

Lab Data: Unknown LABS: Multiple CBC's, wbc, plt and lymphocyte counts high, multiple CMP's, Chloride high, UA wnl, Urine drug screen, + for benzodiazepines and barbituates, Homocystine, Prolactin, Lyme test, EBV, Vit B12 all wnl Dx studies: CT's o

History: None PMH: None Allergies: latex, peanuts, Nicotine patch

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364363-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Oct-2009	26-Oct-2009	0	02-Nov-2009	10-Nov-2009	WI		10-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3067AA	0	Left leg	Intramuscular	
	HPV4	MERCK & CO. INC.	0249Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Syncope, Upper respiratory tract infection

Symptom Text: Fainting spell after administration of vaccines followed by 5 sec sz like movements.

Other Meds: none

Lab Data: Accucheck

History: none known

Prex Illness: URI sx's

Prex Vax Illns:

Vaers Id: **364364-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	26-Oct-2009	26-Oct-2009	0	02-Nov-2009	10-Nov-2009	MA		10-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Headache, Injection site pain, Myalgia, Nausea

Symptom Text: Rec'd 3rd dose of GARDASIL and 4 hrs later felt nauseous, weak, myalgias, headache, arm pain at injection site. Feeling better today with less symptoms.

Other Meds: YASMIN 28 3 0.03 mg

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364426-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		30-Oct-2009	10-Nov-2009	--		10-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site scar

Symptom Text: Patient received the first injection of Gardasil and at the injection site, extreme scar tissue and it seems like the muscle has huge divot to the bone in it. Patient has been to the doctor and a dermatologist and they are contacting the company that makes the drug.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364452-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Jun-2009	30-Jun-2009	0	02-Nov-2009	04-Nov-2009	TX	TX090040PU	20-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: PATIENT ARRIVED FOR HPV #2, STATED LAST MENSTRUAL PERIOD WAS LAST DAY OF MAY 2009 AND SHE WAS NOT PREGNANT. COPY OF CONSENT MAILED. MOTHER INFORM TODAY 7/17/09 AT 11:15 AM PATIENT WAS PREGNANT. MOTHER REQUEST TO BE PLACE IN THE LIST OF HPV BY MERCK.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364497-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Jan-2009	12-Jan-2009	0	02-Nov-2009	05-Nov-2009	TX	TX090046PU	20-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	2	Right arm	Unknown	
	HEP	MERCK & CO. INC.	0399X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness

Symptom Text: BP 98/55 P 72 11 AM PATIENT RECEIVED A HEP B (LEFT ARM) AND A HPV (RIGHT ARM) LOSS OF CONCIOUSNESS FOR APPROXIMATELY 30 SECONDS AFTER RECEIVING THE VACCINES. HER 4 YEAR OLD DAUGHTER RECEIVED VACCINES PRIOR TO PATIENT'S INJECTIONS. 911 WAS CALLED PATIENT REFUSED TO BE TRANSPORTED. BP 114/85 P 82 5 MINUTES LATER.

Other Meds: NONE

Lab Data: GLUCOSE 80

History: DENIES ANY PRE-EXISTING CONDITIONS

Prex Illness: WELL ADULT

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364530-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Oct-2009	31-Oct-2009	1	02-Nov-2009	04-Nov-2009	UT		04-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Hypoaesthesia, Hypoaesthesia facial, Vomiting

Symptom Text: Headache vomiting, numbness in hands and face. Patient transported to Medical Center.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364578-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Jul-2009	20-Jul-2009	0	02-Nov-2009	05-Nov-2009	KY		15-Feb-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1497X	0	Right arm	Unknown	TDAP
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	1	Left arm	Intramuscular	VARCEL
VARCEL	MERCK & CO. INC.	0732Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Arthralgia, Chest pain, Conjunctivitis, Eye discharge, Headache, Malaise, Musculoskeletal pain, Myalgia, Nasal congestion, Pain in extremity, Reflux oesophagitis

Symptom Text: I don't know the exact date, it seems to have been on going for the last 2-3 months. She complains of headaches almost constantly, also stomach aches/pain. She has periodic chest pain, leg pain (mostly knees and hips) and overall just not feeling well. ```records received 11/24/09 & 02/09/2010. Immunization rec. and Clinic rec for DOS 07/20/09. Reason for visit: School physical Assessment: Normal physical examination. Healthy 11 yr. WF individual. Record reflect immunizations given 07/20/09. Database updated. ```records received 02/12/2010. Clinic records for DOS 08/07/09-01/20/2010. Assessment: Reflux esophagitis, abdominal pain, conjunctivitis. Patient presents c/o chest hurts, head hurts, stomach hurts, pink crusty eyes. Patient has pain in lower chest and R. shoulder pain with movement. Findings: tenderness felt on ANT lower intercostal muscles and pain with stretching. Nose congested. Plan. start Zantac, Claritin, stool softener, Vigamox

Other Meds:

Lab Data: ``` 02/12/2010 LABS and DIAGNOSTICS: ALK PHOS TOTAL-217 (H).

History: None ``` 11/24/09: NKDA.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364602-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-Oct-2009	28-Oct-2009	7	02-Nov-2009	10-Nov-2009	AZ		11-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	1	Gluteous maxima	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain

Symptom Text: Soreness in R buttock. Palpable cystic mass deep into injection site C/W abscess. Given Rx for AUGMENTIN

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364622-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Aug-2008	22-Aug-2009	365	03-Nov-2009	05-Nov-2009	TX	TX090050PU	20-Jan-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB235BA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	
MEN	UNKNOWN MANUFACTURER	U2662AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3027AA	5	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	D271X	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash erythematous

Symptom Text: WITHIN 5 MINUTES AFTER RECEIVING SHOTS, RASH AND ITCHING BEGAN ON HANDS, WRISTS, AND ARMS (SMALL, RED, RAISED BUMPS) 25 MG BENADRYL PO VITAL SIGNS P68, RR14, BP 110/70. OBSERVATIONS FOR 1 HOUR POST VACCINATION WITH NO WHEEZING OR DISTRESS NOTED. SYMPTOMS SUBSIDED WITH BENADRYL.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **364707-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	27-Sep-2009		03-Nov-2009	04-Nov-2009	FR	WAES0910USA03222	04-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1697U		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Oedema peripheral, Pruritus

Symptom Text: Information has been received from a nurse concerning a 17 year old female who was vaccinated with a dose of GARDASIL (0.5ml, IM, lot# 1697U, batch# NJ02590). On 27-SEP-2009 the patient experienced intense itching on feet and hands and her feet was very swollen. The adverse events lasted 6 days. The patient was unable to attend school for 1 day. The patient was unable to wear close shoes. Therapy with GARDASIL was discontinued. The patient sought medical attention. At the time of the report, the patient had recovered on 02-OCT-2009. Intense itching on feet and same itching on hands and very swollen feet were considered to be disabling.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 364708-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2009	01-Apr-2009	0	03-Nov-2009	04-Nov-2009	FR	WAES0910USA03152	04-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Angiogram normal, Headache, Migraine, Nuclear magnetic resonance imaging normal, Syncope, Thyroid function test normal

Symptom Text: Information has been received from a pharmacist concerning a 16 year old female patient with no pertinent medical history, who had received a dose of GARDASIL (dose, batch number not reported) approximately 6 months before this report (approximately in April 2009). Five days after vaccination, she experienced a syncope, which increasingly recurred. The patient had a scan, consulted a pneumologist and a cardiologist (date unspecified). Work-ups for cardiology were normal. The patient was hospitalized and had been off school for the last three months. No diagnosis was established. At the time of the report the outcome was not provided. Additional information was received through telephone call to the pharmacist on 28-OCT-209. The syncope was due to headaches, also reported as migraines and very severe. The events started after the second dose of GARDASIL, (lot number and batch number not reported). The patient was concomitantly taking a contraceptive pill that was stopped at the beginning of the symptoms. She was actually taking DOLIPRANE for her migraines, but it had no suppressive effect. MRI and angiography were normal. Thyroid work-up was normal too. The patient under went a session of hypnosis which was followed by period of 24 hours without symptoms. It was planned to put ear aerating device to test if the patient was suffering from undetected secretory otitis media. To be noted that the patient had experienced multiple otitis during her childhood. There was no history of migraine in her family. Other business partner numbers included E2009-09953. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Otitis

Prex Vax Illns:

Vaers Id: **364709-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		03-Nov-2009	04-Nov-2009	--	WAES0910USA02674	04-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Non-Hodgkins lymphoma

Symptom Text: Information has been received from a registered nurse concerning her approximately 16 year old sister in law's daughter who on an unspecified date was vaccinated with a dose of GARDASIL (Lot number unspecified). The registered nurse reported that the patient was diagnosed with Non-Hodgkin's lymphoma after vaccination with GARDASIL. At the time of the report the status of the patient was unspecified. The patient sought medical attention. Upon internal review, Non'Hodgkin's lymphoma is considered to be an other important medical event. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **364710-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		03-Nov-2009	04-Nov-2009	IL	WAES0910USA02673	04-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Coma, Neurological symptom

Symptom Text: Information has been received from a physician who heard from a Nurse concerning a young female who was vaccinated on an unspecified date with GARDASIL (Lot number was not available). The reporter stated that the patient experienced neurological side effects and entered a coma for a length of time after receiving GARDASIL. It also was stated that the patient "had gone through a lot of things but they felt it was from GARDASIL because of process of elimination". It was reported that "unspecified test" were performed on an unknown dates. The reporter mentioned that the patient was hospitalized for an unspecified length of time. At the time of reporting the patient had not recovered. "Attempts are being made to verify the existence of an identifiable patient". Additional information had been requested. Patient was hospitalized.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **364711-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Apr-2008	15-Apr-2008	0	03-Nov-2009	04-Nov-2009	WI	WAES0805USA05666	04-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Failed induction of labour, Pre-eclampsia

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy Registry product, concerning a 20 year old female with a history of polycystic ovarian syndrome who on 15-APR-2008 was vaccinated IM with the first dose of GARDASIL (655327/1287U). Concomitant therapy included PROMETRIUM and Metformin. The physician reported that the patient is pregnant (LMP = 23-MAR-2008) and that gestation is 2 days prior to vaccination. The patient sought unspecified medical attention in the physician's office. Prenatal labs were performed; results were normal. No adverse effects were reported. Patient outcome was not reported. Follow up information was received from a health professional who initially reported that the patient had a pregnancy and delivery with "no complications". The health professional later stated, "that the patient was not without complications since the patient had pre-eclampsia and also had a cesarean section." Follow up information was received from the physician who stated that the patient had a healthy and normal male, with no congenital anomalies. He was born full-term and weighed 6lb, 8oz. Additionally, the patient had a history of chronic hypertension and developed pre-eclampsia, for which she was induced at 37 weeks gestation. Her induction failed and as a result the patient had a cesarean section, from which she has recovered "just fine". At the time of the report the patient was pregnant again. Upon internal review cesarean section was considered to be an other important medical event. Additional information is not expected.

Other Meds: Metformin; PROMETRIUM

Lab Data: Blood chemistry, normal

History: Polycystic ovarian syndrome

Prex Illness: Pregnancy NOS (LMP = 3/23/2008); Hypertension

Prex Vax Illns:

Vaers Id: **364712-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Aug-2008	18-Dec-2008	136	03-Nov-2009	04-Nov-2009	NJ	WAES0909USA00375	01-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection, Surgery, Vaccination failure

Symptom Text: Information has been received from a physician concerning a 19 year old female patient with penicillin allergy who was vaccinated intramuscularly with 3 doses (0.5ml each one) of GARDASIL on 31-JAN-2008 (lot #659962/0571X) respectively. The physician reported that the patient had a PAP smear that was positive to all 4 types of GARDASIL. Prior to starting the GARDASIL vaccine the patient had a PAP smear that was negative to all 4 types of GARDASIL (date not reported). A biopsy from a PAP smear was done on 18-DEC-2008 showed the patient has 13 high risk types of HPV and 5 low risk types of HPV, this information came from the patient's obstetrics and gynecology physician. Also performed were "serologic test for other sexually transmitted diseases" but the results were not reported. The patient sought medical attention in the office visit. The outcome was reported as not recovered. Follow-up information was received from a physician via medical records. It was reported that the patient with a history of unspecified vaginitis and vulvovaginitis was vaccinated into the right arm with the first dose of GARDASIL (lot # 659962/1740U) on 31-JAN-2008 at 10:00, with the second dose of GARDASIL (lot # 659962/1740U) into the left arm on 15-MAR-2008 at 10:00 and with the third dose of GARDASIL (lot # 659962/0571X) into the right arm on 04-AUG-2008 at 10:30 respectively. The physician reported that the patient had a PAP smear that was positive for multiple papillomas strains of HPV; including the ones in the vaccine. The pap sample collected on 18-DEC-2008 was sent for HPV testing and results reported on 29-DEC-2008. The patient's test results were reported as (patient had Pap IG, HPV-h+Ir) Epithelial cell abnormality, atypical squamous cells of undetermined significance. HPV results: HPV, high-risk: positive; HPV low-risk: negative. The physician reported that event required medical/surgical intervention. Additional information was received from the physician. It was reported that the physician felt that "the vaccine did not wo

Other Meds: None

Lab Data: biopsy, 12/29/08, HPV results: HPV, high-risk: positive; HPV low-risk: negative; biopsy, 12/29/08, epithelial cell abnormality, atypical squamous cells of undetermined significance; colposcopy, results not provided; clinical serology test,

History: Vaginitis; Vulvovaginitis

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **364726-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	21-Oct-2009	21-Oct-2009	0	03-Nov-2009	11-Nov-2009	NH		11-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3250AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Dysarthria, Dyspnoea, Hypoaesthesia, Hypoaesthesia facial, Injection site anaesthesia, Pruritus, Urticaria

Symptom Text: Developed itching night of vaccines. Woke up with hives the next morning. Took BENADRYL and didn't help. Developed chest heaviness and couldn't breath. Bilateral face numbing. Left chest and Left arm felt numb. Went to hospital due to trouble breathing and slurred speech. ER gave her IV STEROIDS, BENADRYL, PEPCID. She required 60 mg total of SOLUMEDROL. Pt went home from hospital on 4 more days of STEROIDS and finished the dose of 60 mg. Pt also took BENADRYL intermittently.

Other Meds: Xyzal 5mg

Lab Data: None

History: Cephalosporins, Keflex; Claritin, Penicillin

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364749-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Nov-2009	03-Nov-2009	0	03-Nov-2009	05-Nov-2009	TX		05-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Nausea, Syncope, Tonic clonic movements, Unresponsive to stimuli

Symptom Text: pt recieved injection left deltoid at 10:15 am while sitting in chair; pt c/o nausea immediately after; had syncopal episode while sitting in the chair. Pt noted to have tonic-clonic motion with syncopal episode. Pt unresponsive for brief second of time; responsive immediately with vital signs of 10:25am: 92/59 b/p, 58 hr, 98% oxygen sat; 10:35am: b/p 122/69 and 76 hr. pt was transport to ER via amublance transport.

Other Meds:

Lab Data: no known at time of this submission; pt is in the ER.

History: none

Prex Illness: no illness noted

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364776-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	03-Aug-2009	31-Aug-2009	28	03-Nov-2009	11-Nov-2009	NY		17-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Pt received GARDASIL #1 on 8/3/09. Pt returned to office 8/31/09 and was pregnant. Lmp 7/25/09

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 364877-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	30-Sep-2009	30-Sep-2009	0	04-Nov-2009	11-Nov-2009	NC		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: LPN calls FBVHC on 29OCT09 re 23 y/o AD female SM who inadvertently received GARDASIL vaccine on 30SEP09 and the Live Intranasal Flumist vaccine on 08OCT09 before the SM knew she was pregnant. As of 29OCT09, when the SM's OB Intake/Registration was performed the SM was at 6 weeks, 3 days gestation / LMP 12SEP09 / EDC 19JUN2010. Age at first pregnancy: 20 years. Gravida 3, para 0 and 2 abortions/miscarrages one at 9 weeks and one at 5 months. No previous ectopic pregnancies. No h/o congenital malformations. No DES taken during pregnancy. Baby's father is 24 y/o. The SM currently denies any evidence of adverse events following immunizations received no spotting, cramping, pelvic or abdominal pain reported. Denies N or V. NKDA. The SM is scheduled to be seen at OB-GYN on 07DEC09 for specialty consult s/p vaccine exposure as noted above. SM advised to notify PCM of any new onset of spotting, pelvic or abdominal cramping or pain. Intractable N or B fever > 101F or any other changes in health status. FBVHC provided patient with online resources for MERCK GARDISIL PREGNANCY REGISTRY and will F/U with SM periodically throughout pregnancy to inquire re progress and reporting of any adverse events up through the delivery of the baby. Symptoms: Amenorthea.

Other Meds: Prenatal Vitamins w/ Ferrous Fumarate 28mg & Folic Acid 0.8mg.

Lab Data: Pregnancy confirmed by POSITIVE Beta Serum hCG (19OCT09). NEGATIVE Chlamydia trachomatis & Neisseria gonorrhoeae rRNA Panel (30Sep09) and PAP SMEAR 930SEP09) was NEGATIVE for Intraepithelial lesion or malignancy.

History: Condyloma acuminatum

Prex Illness: None

Prex Vax Illns:

Vaers Id: **364887-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Aug-2009	21-Aug-2009	0	04-Nov-2009	05-Nov-2009	OH		06-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye pruritus, Headache, Vomiting

Symptom Text: APPROX 2 HOURS AFTER INJECTION, PT C/O ITCHY EYES, HEADACHE ALL OVER AND EMESIS FOR 2-3 HOURS. SPOKE WITH THE DOCTOR ON CALL AND SENT TO EMERGENCY ROOM. PT TREATED WITH ANTI-EMETICS, VITAL SIGNS STABLE AND PATIENT WAS DISCHARGED

Other Meds: KARIVA-28

Lab Data: NONE

History: MENORRHAGIA AND DYSMENORRHEA

Prex Illness: NONE PER PATIENT

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364913-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Oct-2009	27-Oct-2009	0	04-Nov-2009	11-Nov-2009	IN		11-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Eye swelling, Swelling face

Symptom Text: GARDASIL given on 10-27-09. Mother calls 10-29-09 and states patient had puffy face and eyes the afternoon of 10-27-09. States c/o chest tightness either late PM 10-27 or 10-28 and continues today. BENADRYL 25 mg TID and go to ER for increased sx.

Other Meds: Depo-Provera last dose 8-27-09

Lab Data:

History: Lortabs-per patient

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364964-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	23-Apr-2009		04-Nov-2009	05-Nov-2009	WI	WAES0907USA04172	05-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Fatigue, Myalgia, Nausea, Pain, Vomiting

Symptom Text: Information has been received from a medical assistant, for GARDASIL, a Pregnancy Registry product, concerning a 22 year old female with penicillin allergy who on 05-DEC-2008 was vaccinated with the first dose of GARDASIL (lot number unspecified). On 03-FEB-2009 the patient received the second dose of GARDASIL (lot number unspecified). On 10-JUL-2009 the patient received the third dose of GARDASIL (lot number: 661846/1312X, 0.5ml, IM. There was no concomitant medication. The patient's last documented period was 3 months ago, in approximately April 2009; however, the patient had sporadic periods. On 23-JUL-2009, the patient was seen in the office for symptoms of body aches, fatigue, nausea, vomiting and myalgia. On 23-JUL-2009 a urine pregnancy test was conducted and the result was positive for pregnancy. HCG quantitative test was ongoing (result unknown). The patient's estimated delivery date would be on 28-JAN-2010. At the report time the patient was pregnant. Follow up information has been received from a medical assistant concerning the 22 year old female who was vaccinated with 3 doses of GARDASIL on 05-DEC-2008, 03-FEB-2009 and 10-JUL-2009 respectively. The reporter noted that the patient terminated pregnancy on an unspecified date. The patient last menstrual period was on 27-APR-2009. The estimated delivery date (EDD) would be on 01-FEB-2010. At the time of the report, the outcome was unknown. No further information is available.

Other Meds: None

Lab Data: urine beta-human, 07/23/09, positive for pregnancy

History:

Prex Illness: Pregnancy NOS (LMP = 4/27/2009); Penicillin allergy

Prex Vax Illns:

Vaers Id: **364965-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	30-Oct-2009	30-Oct-2009	0	04-Nov-2009	05-Nov-2009	FR	WAES0910POL00011	05-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Aphasia, Blood pressure decreased, Grand mal convulsion, Intensive care

Symptom Text: Information has been received from a physician concerning a female, without any allergy in medical history, who on 30-OCT-2009 was vaccinated with the first dose of GARDASIL. Concomitant therapy included THERAFLU. About 30 minutes after vaccination the patient experienced blood pressure decreased. About one hour after vaccination the patient experienced tonoclonic convulsions. The patient was admitted to the hospital (intensive care unit). The patient was conscious, she understand everything, she could write, but she could not talk (she experienced aphasia). The patient's tonoclonic convulsions and aphasia persisted. The reporter felt that blood pressure decreased, tonoclonic convulsions and aphasia were related to therapy with GARDASIL. Upon internal review tonoclonic convulsions were determined to be an other important medical event. Additional information has been requested.

Other Meds: acetaminophen (+) chlorpheniramine malea Oct09 - 23?Oct09

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **364968-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Feb-2008	22-May-2008	87	04-Nov-2009	05-Nov-2009	--	WAES0910USA03932	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1570X	3	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia facial, Pain in jaw, Wheelchair user

Symptom Text: Information has been received from a consumer concerning a female family friend who on unspecified date was vaccinated with GARDASIL (dose number, lot number not reported). The patient developed numbness and was in a wheelchair after vaccination. The patient saw a neurologist. It was unknown if there were lab studies performed. At the time of the report, the outcome of the patient was not reported. Upon internal review, being in a wheelchair was considered to be disabling. This is one of several reports from the same source. Additional information has been requested.11/23/2009 PCP records 7/23 and 5/30/2008, patient with c/o's facial numbness. rt lip numbness, jaw soreness and clenching. No tx noted. no labs noted

Other Meds: Unknown

Lab Data: Unknown

History: Unknown PMH: None Allergies: NKDA

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **364970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Sep-2009	17-Sep-2009	0	04-Nov-2009	05-Nov-2009	FR	WAES0910USA04167	05-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ29430	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Asthenia, Confusional state, Hypertonia, Muscle rigidity, Petit mal epilepsy

Symptom Text: Case received by Health Authority (case # 104968) through (local case # IT434/09). Initial report received on 22-OCT-2009. Information has been received from a health authority concerning an 11 year old female patient with no medical history for intolerance and/or disease who on 17-SEP-2009 was vaccinated intramuscularly with the first dose of GARDASIL (batch# NK19200, lot# NJ29430). There were no drugs or vaccines administered during the 4 weeks prior to vaccination. On the same day, a few minutes post vaccination, the patient developed rigidity with hypertonia that lasted a few seconds, accompanied by apparent state of absence and asthenia, sub-confusional state and complete amnesia about the event. Health authority only code "absence seizure". She was laid supine with her legs raised. The event resolved spontaneously on 17-SEP-2009. The case was reported as not serious by both the reporter and the health authority and was updated to serious (other important medical event) by company upon medical review. The case is closed. Other business partner numbers included: E2009-09922. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **365004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Jan-2009	19-Apr-2009	94	04-Nov-2009	12-Nov-2009	OK		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Headache, Lethargy, Tonic clonic movements

Symptom Text: Seizures, seizure meds. 12/3 and 12/10/2009 PCP records from 11/2008-10/2009 and ED record for 11/8/2009. Patient with c/o's tonic-clonic seizure activity, with postictal headache, lethargy and confusion. Patient has a hx of seizure d/o since 4/2009, has been taking Keppra, Keppra dosage increased and Lamictal added

Other Meds:

Lab Data: EEG Labs: CBC and CMP wnl, Urine and serum drug screen all negative Dx studies: EEG abnormal spikes in parietal temporal region, MRI abnormal noting a small cystic lesion medial rt temporal lobe of uncertain etiology, CT Head wnl

History: PMH: Seizure Disorder Allergies: NKDA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **365026-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Sep-2009	08-Oct-2009	16	04-Nov-2009	11-Nov-2009	OH		04-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1009Y	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	
FLU	SANOFI PASTEUR	U3173AA	0	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Computerised tomogram normal, Epilepsy, Loss of consciousness, Syncope, Urinary incontinence

Symptom Text: Pt had a syncopal episode (? seizure) on 10/8/09. Taken to ER, normal head CT. Followed up with neurology a week later and EEG showed epilepsy. Mom called our office on 10/19/09 to report the events. She was not hospitalized & has had no more syncope or seizures to my knowledge as of 10/20/09. 11/23/2009 ED records for 10/8/2009. Patient with c/o's "passing out" and urine incontinence.

Other Meds:

Lab Data: Sleep EEG - epilepsy Labs: CBC, Mag, BMP, HCG, all normal Dx studies: Ct Head and EKG normal

History: Former 27 week triplet; history of iron deficiency; anemia PMH: Iron deficiency anemia Allergies: NKDA

Prex Illness:

Prex Vax Illns:

Vaers Id: **365287-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		05-Nov-2009	06-Nov-2009	--	WAES0910USA03897	06-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with a dose of GARDASIL. The physician reported that during the visit of another patient the patient's mother refused to give the second dose of GARDASIL to her daughter because "a friend of the patient received GARDASIL and was paralyzed". The patient's outcome was unknown. It was unknown if the patient sought medical attention. Upon internal review paralysis was considered to be an other important medical event. Attempts are being made to verify the existence of an identifiable patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **365289-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jun-2009	01-Jun-2009	0	05-Nov-2009	06-Nov-2009	FR	WAES0910USA04032	06-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Rash maculo-papular

Symptom Text: Information has been received from Health Authorities (reference # C200909-1137) concerning a 17 year old female with no previous adverse reactions to GARDASIL and other drugs, who in June 2009 was vaccinated with a dose of GARDASIL (batch # not reported) IM. Five days after vaccination, the patient developed a maculo-papular exanthema which resolved after 10 days. The drug was suspended and the patient was given oral anti-histamines and topical corticosteroids as corrective treatment. To be noted that the case was received as a follow-up by the Health Authorities, although the initial version had not been received. Furthermore, after the meeting of the unit, the case was updated to serious by the Health Authorities (follow-up consisted in upgrading). At the time of the report, the patient had recovered. Maculo-papular exanthema was considered to be an other important medical event. Other business partner numbers included E2009-10100. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **365292-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-Oct-2009	28-Oct-2009	1	05-Nov-2009	06-Nov-2009	LA	WAES0910USA04075	18-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF486AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0070X	2	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Syncope, Vaccination complication

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter with no medical history or drugs allergies, who in May 2009, was vaccinated with her first dose of GARDASIL. The patient received her third dose of GARDASIL on 27-OCT-2009. There was no concomitant medication. On 28-OCT-2009 the patient had a seizure and was hospitalized; the physician at the hospital stated that GARDASIL caused the seizure. No laboratories studies were performed to the patient. At the time of this report the patient was recovering. Additional information has been requested. 11/20/09 Hosp. records received for dates 10/28/09. DX: syncope. Presenting sx: pt. states passed out and hit head at school. Pt received immunizations 1 day ago. Pt. had a seizure that lasted approx. 10 mins. Was taken to hospital by ambulance. Was given "2 shots" per mth. and being referred to a neurologist. Reported by mth. today (11/9/09).

Other Meds: Received MPA in clinic on 10-27-09

Lab Data: None 11/20/09 Hosp. records received for dates 10/28/09. Diag/Labs: troponin(-), TSH WNL, CXR(-), CT brain(-), EKG WNL.

History: None 11/20/09 Hosp. records received for dates 10/28/09. PMH: sulfa allergy

Prex Illness: None

Prex Vax Illns:

Vaers Id: 365296-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Apr-2009	01-Apr-2009	0	05-Nov-2009	06-Nov-2009	--	WAES0910USA04077	09-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Computerised tomogram, Concussion, Dizziness, Eye pain, Fatigue, Headache, Loss of consciousness, Migraine, Nausea, Pain, Photophobia, Photosensitivity reaction, Syncope, Tension headache, Visual impairment

Symptom Text: Information has been received from an office manager concerning her daughter with no pertinent medical history and no known allergies who on April 2009, was vaccinated with the second dose of GARDASIL. There was no concomitant medication. In April 2009, two days after administration of the second dose of GARDASIL, the patient experienced migraines, syncope and aches. It was reported that the patient's symptoms "come and goes and go with different durations". On an unspecified date a computerized tomography was performed; results were not reported. The patient's mother stated that her daughter had to miss one month of school. At the time of reporting the patient had not recovered. The reporting office manager considered that migraines, syncope and aches were disabling. Additional information has been requested. 11/16/09: Neurology consult received for date of service 5/8/09. Dx: HA's and Migraine HA's Assessment: Initially she sees spots that resolve, then she becomes dizzy, followed by HA pain. Pain starts in R frontal region, with eye pain then becomes diffuse throughout her head. She experiences nausea, photophobia, feet and ankles become tingly with diffuse weakness and fatigue. All sx. resolve once the HA resolves. HA's occur monthly. Hx. of migraines for one year lasting hours to days. Migranes intensified after a concussion with a brief loss of consciousness 1 yr. ago. Tension HA's occur up to a couple of times per wk. Most recent migraine lasted for a few weeks. Taking Frova, Amitryptyline and Compazine prn. 11/24/09 ER records received for date 4/14/09, 4/24/09, 4/28/09, 4/29/09. DX: migraine. Chief c/o migraine HA, nausea, x2 wks. Assessment:WNL, pt tx, and dc w/ sx resolved.ER visit on 4/29/09 DX: migraine HA. Pt c/o ongoing HA/migraine x3wks. HA moves to different locations of head. Pt states sharp pain/pressure, nausea, light/sound sensitive. Pt. states have blacked out a couple of times.

Other Meds: None

Lab Data: Unknown. 11/16/09: Neurology consult received for date of service 5/8/09. Labs and diagnostics: None. 11/24/09 ER records received for date 4/14/09, 4/24/09, 4/28/09, 4/29/09. Diag/Labs: blood test WNL.

History: None. 11/16/09: Neurology consult received for date of service 5/8/09. PMH: Concussion. 11/24/09 ER records received for date 4/14/09, 4/24/09, 4/28/09, 4/29/09. PMH: migraines

Prex Illness:

Prex Vax Illns:

Vaers Id: **365339-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Nov-2009	04-Nov-2009	0	05-Nov-2009	05-Nov-2009	IA		09-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2932AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3248AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient received the injection of Gardasil and within seconds fainted. Within a minute the patient was again alert.

Other Meds:

Lab Data: None

History: None Known

Prex Illness: None Known

Prex Vax Illns:

Vaers Id: **365361-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Feb-2007	01-Jul-2007	143	05-Nov-2009	06-Nov-2009	FL		06-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Cervical dysplasia, Fungal infection, Infectious mononucleosis, Pharyngitis streptococcal, Precancerous cells present, Skin papilloma, Surgery, Urinary tract infection

Symptom Text: TOOK GARDASIL VACCINE FEB 2007 WHEN I WAS 25. I WAS A VIRGIN AND HAD NO PRIOR ABNORMAL PAPS OR HEALTH PROBLEMS. MY LEG DEVELOPED A HUNDRED PINPOINT WARTS JUNE/JULY 2007 AND WENT TO DERMATOLOGIST. TOOK 1 1/2 YEARS TO GO AWAY. MY FIRST ABNORMAL PAP SMEAR WAS THAT FALL, SEPT 2007. BIOPSY SHOWED MILD DYSPLASIA. WENT AWAY AFTER 6 MONTHS BUT MILD DYSPLASIA CAME BACK IN SEPT. 2009. NEED SURGERY NOW TO REMOVE PRECANCER CELLS IN CERVIX. ALSO DEVELOPED MONO, STREP THROAT SEVERAL TIMES, URINARY TRACT INFECTIONS, AND FIRST YEAST INFECTION SINCE TAKING VACCINE SHORTLY AFTER. NEVER FELT THE SAME SINCE.

Other Meds: ORTHO TRI CYCLEN AND SINGULAIR

Lab Data: ANNUAL PAPSMEAR 2007-ABNORMAL. BIOPSY WAS MILD DYSPLASIA. TOOK ANOTHER 3 MONTHS LATER AND ABNORMAL. 3 MONTHS LATER THEN NORMAL. NEXT ANNUAL IN SEPT 2008 WAS NORMAL. ANNUAL IN SEPT 2009 WAS ABNORMAL. BIOPSY SHOWED MILD DYSPLASIA.

History: ASTHMA

Prex Illness: NO. HEALTHY

Prex Vax Illns: 07/01/2007~HPV (Gardasil)~3~25.83~Patient

Vaers Id: **365363-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	31-Mar-2009	24-Apr-2009	24	05-Nov-2009	06-Nov-2009	--		24-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0615X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Cerebral venous thrombosis, Headache, Influenza like illness, Lymphadenectomy, Mononucleosis heterophile test positive, Nausea, Vomiting

Symptom Text: Patient developed a cerebral venous thrombosis post vaccination. Patient hospitalized and placed on coumadin for 6 months. 11/24/09 ER records received for date 4/24/09 to 4/25/09. DX: venus sinus thrombosis, mononucleosis. Pt Presented w/ left sided transverse sinus thrombosis via CT scan results. SX: HA x2wks, N&V, flu like symptoms, cervical lymphadenopathy on left side. Assessment: (+)HA, otherwise WNL. Pt started on anticoag. tx and dc following day stable.

Other Meds: Oral contraceptives

Lab Data: 11/24/09 ER records received for date 4/24/09 to 4/25/09. Diag/Labs: MRI abnormal, blood test WNL.

History: Patient on oral contraceptives at time of reaction. 11/24/09 ER records received for date 4/24/09 to 4/25/09. PMH: asthma, mononucleosis(+), BCP.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **365386-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	03-Nov-2009	04-Nov-2009	1	05-Nov-2009	06-Nov-2009	MI		09-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF500AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0978Y	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain, Injection site swelling

Symptom Text: Patient noticed sore raised area on the posterior upper part of her arm day after injection (at injection site) about the size of a 50 cent piece. Day two (11/5/09) indurated area was 10 times bigger, red and sore to touch.

Other Meds: Lisinopril 30mg 1 daily Ortho Micronor 0.35mg 1 daily Dextromethorphan-Guaifenesin 10-300mg/5ml 1-2 teaspoons four times a day as needed for cough and congestion.

Lab Data: none

History: motrin-hives

Prex Illness: sore throat and cough x 3 days.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **365420-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Nov-2009	03-Nov-2009	0	05-Nov-2009	06-Nov-2009	HI		09-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C3247AA	5	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3020AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB357AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Flushing, No reaction on previous exposure to drug, Tachycardia, Wheezing

Symptom Text: flushing, wheezing, tachycardia about 30 minutes after receiving vaccines. Went to the ED and received albuterol updraft, IV benadryl and solumedrol with marked improvement and sent home on oral prednisone and benadryl. Has had 5Dtap's previously and all her immunizations without any previous adverse reactions.

Other Meds: Cleocin T gel; Differin gel for acne

Lab Data: none

History: Cow's milk allergy; intermittent asthma

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **365427-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Apr-2007	30-Aug-2007	122	05-Nov-2009	06-Nov-2009	CA		12-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1447F	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aggression, Amnesia, Asthma, Convulsion, Disorientation, Dizziness, Fatigue, Flat affect, Incoherent, Incontinence, Lacrimation increased, Unresponsive to stimuli

Symptom Text: Started passing out at school, incoherent and did not recognize people. Was taken to hospital emergency complete blood work including drug testing done, all came back negative. CAT scan done came back negative. Unable to recognize family member that came to hospital and friends. While in hospital she had what we now know 3 seizures. She becomes completely quiet, tears running down face and does not respond to any one. They released her saying it was a reaction to her asthma inhaler. Went to pediatrician next day who thought it may be drugs but drug panel at hospital was negative. Her personality completely changed went from outgoing and friendly, to quiet and tired. On Wednesday September 5 she returned to the pediatrician who suggested she see a specialist she suspected patient was having seizures and her memory had still not returned. Started seeing Dr. on Sept. 6 and he confirmed seizures put on meds. After seizures she becomes very aggravated and mean then take a nap that can last anywhere from a couple hours to all day. There were 2 occasions she lost control of her bodily functions. In October she started have short term memory loss and would ask the same question over and over again. She was taken out of school and put on hospital/home studies for the remainder of her sophmore year. She was taken off all med in the spring of 2008 and her last seizure was in Nov of 2008. 12/16/09 Medical records received for dates 9/16/07 to 3/14/08. DX: seizures. Multiple f/u appts for seizure monitoring. Pt w/ active seizure disorder. 12/17/09 ER records received for date 8/30/07. DX not documented. SX: c/o asthma attack, parents states pt not acting right since the asthma attack. Assessment: flat affect, disoriented. 1/4/2010 Ed note for 9/20/2007, patient with c/o's dizziness, no tx noted,

Other Meds:

Lab Data: CAT Scan, EEG, MRI, Blood work ups Diag/Labs: CT(-), UA(-), tox screen(-), MRI(-), EEG abnormal.

History: asthma Allergies: NKDA

Prex Illness: none

Prex Vax Illns:

Vaers Id: **365497-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Nov-2009	04-Nov-2009	0	05-Nov-2009	12-Nov-2009	PA		20-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling hot, Throat tightness

Symptom Text: Mother stated that 10 minutes after the patient received the GARDASIL vaccine, the patient reported to have a tight feeling in her throat and the patient started to feel hot. Patient was told by doctor to wait 10 minutes and symptoms should go away.

Other Meds: Vitamins

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **365545-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Jan-2008	01-Jul-2008	182	06-Nov-2009	09-Nov-2009	FR	WAES0911CAN00002	17-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Death, Drug exposure during pregnancy, Foetal disorder, Premature labour, Stillbirth

Symptom Text: Information has been received from a 22 year old female with a history of precancerous cells present (caused by HPV) in 2004 and partial cervicectomy who in approximately January 2008, was vaccinated with the first dose of GARDASIL, lot # not available. In approximately March 2008, the patient was vaccinated with the second dose of GARDASIL, lot # not available. In July 2008 the patient found out she was pregnant. In September 2008 the patient was vaccinated with the third dose of GARDASIL, lot # not available (on the recommendation of her physician). In approximately January 2009 the patient went into premature labor (at 23 and a half weeks gestation) and her son was still born. Upon internal review, 23 and a half weeks gestation and stillbirth were considered to be other important medical events. No further information is available. This is one of several reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Precancerous cells present; Cervicectomy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **365578-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Oct-2009	30-Oct-2009	0	06-Nov-2009	12-Nov-2009	AL		12-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Crying, Fear, Pallor, Posture abnormal

Symptom Text: Patient slumped in chair, began seizure - like activity, became pale, then after I tried to get a response from her began crying and stated she was scared.

Other Meds: Depo-Provera

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **365759-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Oct-2009	27-Oct-2009	0	06-Nov-2009	12-Nov-2009	MO		12-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	13324	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Dizziness

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **365902-1 (S)** **Related reports:** 365902-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Jul-2009	05-Oct-2009	67	08-Nov-2009	10-Nov-2009	IN		02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Conversion disorder, Convulsion, Fall, Fatigue, Headache, Hyperventilation, Hypoaesthesia, Hypotension, Pain, Paraesthesia, Paraesthesia oral, Presyncope, Syncope, Tremor

Symptom Text: Patient came to parent reporting numbness and tingling of legs/feet. She fell to the ground and begin seizing. Her aunt, a nurse manager, recognized the symptoms of a seizure and accompanied parent to the ER. She was transported to another hospital and hospitalized 10/05-10/10/2009. Patient has continued to have unexplained seizures since that time. Other symptoms include: low blood pressure, headache, fatigue, hyperventilation, achy and shaky legs. 11/13/09: Discharge summary and hospital records received for dates of service 10/8/09 to 10/13/09. Dx: Psychogenic nonepileptic seizures. Assessment: Presented with episodes of lightheadedness, dizziness, near syncopy or syncopy, numbness of legs & feet, feelings of her lips tingling as well as episodes of hyperventilation. Eventually sx. increased to loss of awareness and seizure-type activity. Seen in the ED 3 times in 24 hrs. prior to admission for apparent seizure activity. Admitted to ICU for observation. Video EEG noted several events judged nonepileptic in nature. The apparent seizures were determined to be a conversion disorder. Pt. discharged to home with instructions to stay home from school, not drive, and to be supervised when bathing. 11/23/09 Hosp. records received for date 10/8/09. DX: Seizure vs pseudoseizure. Presenting SX in ER: active seizure several episodes, upper body shaking, crying. MD witnessed episode, no LOC. Pt. seen in ER 10/7/09 for episodes of hyperventilation. ICD9 codes: 786.01, 780.39, 782.0

Other Meds: None

Lab Data: EKG, various lab workups (urine and blood), CT, MRI and video EEG. 11/13/09: Discharge summary and hospital records received for dates of service 10/8/09 to 10/13/09. Labs and diagnostics: Head CT (-), CBC (WNL), BMP (WNL), TSH (NL), Mag

History: None. 11/13/09: Discharge summary and hospital records received for dates of service 10/8/09 to 10/13/09. PMH: Synovitis of the hip, irritable bowel disorder, sinusitis, rash from Amoxicillin. 11/23/09 Hosp. records received for date 10/8/09 PMH: sinusitis, hyperventilation, low BP.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **365902-2** **Related reports:** 365902-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Mar-2010	23-Mar-2010	--	WAES1003USA02518	23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a consumer via internet newspaper concerning her daughter, who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently the patient was suffering for seizures, a problem her parents were convinced was a result of GARDASIL "shots". It was stated that the Centers for Disease Control stand behind the vaccine, as a safe way to prevent cases of cervical cancer that health officials insist will otherwise kill thousands of women. At the time of the report the patient's outcome was unknown. It was unknown if the patient sought medical attention. Upon internal review seizures was considered to be an other important medical event. This is one of several reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **365909-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	13-Oct-2009	13-Oct-2009	0	08-Nov-2009	09-Nov-2009	IL		17-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness, Fatigue, Lymphadenopathy, Neck mass, Presyncope, Swelling

Symptom Text: Lymph node in neck became swollen. Feeling tried and exhausted and dizzy all day. Cannot perform normal daily functions because of tiredness and near syncope.11/12/2009 MD records for 10/20/2009, patient with c/o's lump lt side of neck. PE noted a small, mobile, 1cm mass. Tx: observation Dx neck mass ICD-9 code 784.2

Other Meds: Birth Control (Seasonique), Asmanex, Albuteral, Mobic

Lab Data: Dx studies: US of the neck impression lymph node

History: asthma PMH: Asthma Allergies: Keflex

Prex Illness: no

Prex Vax Illns:

Vaers Id: 365958-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Jan-2007	01-Jan-2008	356	09-Nov-2009	11-Nov-2009	RI		20-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0243U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Raynauds phenomenon

Symptom Text: The winter following her Gardasil series the patient developed significant Raynaud's Disease. Bloodwork included a + ANA and + RNP antibodies and low white count. So far she has not developed symptoms of SLE or mixed connective tissue disease, apart from general aching, but ANA has been elevated as high as 1:1280 speckled. THere is no family history of autoimmune disorders. Her Raynaud's symptoms continue to be very significant and she is on daily Procardia XL 30 mg, year round. 11/13/09 Medical/lab/ vax records received. OV 10/20/08 DX: Reynaud's syndrome. PE WNL.

Other Meds: None at that time

Lab Data: Persistantly elevated ANA as high as 1:1280, + RNP antibodies and WBC's in the 3K range 11/13/09 Medical/lab/ vax records received Diagnostics/Labs: blood test normal, lupus(-)

History: None 11/13/09 Medical/lab/ vax records received PMH: migraines, Raynauds, anemia.

Prex Illness: No, she also had doses 2/23/2007 and 7/13/2007

Prex Vax Illns:

Vaers Id: 365994-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Oct-2009	14-Oct-2009	0	09-Nov-2009	10-Nov-2009	CA	WAES0910USA04076	10-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal discomfort, Activities of daily living impaired, Dehydration, Dizziness, Fatigue, Headache, Inappropriate schedule of drug administration, Influenza like illness, Photophobia, Pyrexia, Somnolence

Symptom Text: Information has been received from a physician and a registered nurse concerning an 18 year old female patient with shoulder injury who on 02-SEP-2008 was vaccinated with the first dose of GARDASIL (lot # 661530/0575X) and on 14-OCT-2009 received the second dose of GARDASIL (663452/0671Y). There was no concomitant therapy. On 15-OCT-2009, the next day after vaccination, the patient complained of headache, fever and general fatigue. The fever went away after about a day. The headache persisted. It was reported that there was stomach discomfort as well. On an unspecified date, the patient ended up being treated at urgent care with IV fluids for dehydration and IV TORADOL for headache. The physician stated that the patient has been out of school for this entire time and unable to drive because of dizziness and light sensitivity to the eyes. On 27-OCT-2009, the patient called to the office because she thought that she was sick with flu like symptoms. The physician also stated that the patient was debilitated and that she was sleeping 8 to 10 hours a day. It was also reported that the patient could not drive or do anymore of her normal activities. This had been ongoing for 2 weeks as of 28-OCT-2009. No laboratory or diagnostic tests were performed. At the time of reporting the patient was on around the clock pain relievers. Upon internal review the patient's experiences were considered to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Injury to shoulder NOS

Prex Illness:

Prex Vax Illns:

Vaers Id: 365995-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	02-Jul-2007	01-Jan-2008	183	09-Nov-2009	10-Nov-2009	FR	WAES0910USA04142	17-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Erythema, Pruritus, Rash

Symptom Text: Information has been received from a consumer via CSL as part of a business agreement (manufacturer control #20091030KH2) concerning a 25 year old female patient with polycystic ovarian syndrome who on 02-Jul-2007 was vaccinated with the first dose of GARDASIL, on 28-Sep-2007, received her second dose of GARDASIL and on 12-Mar-2008 received her third dose of GARDASIL (Lot numbers not reported). There was on concomitant medication. In approximately January 2008 (reported as beginning of 2008), the patient experienced itchiness and red spots/rash near scalp between cheeks and eyes (developed itchiness and red spots on forehead and underneath eyes) after the administration of GARDASIL. The itchiness went away but redness remained after a while. The patient also experienced joint pain in ankles and wrists. In the beginning of 2009 an arthritis test was done and the results were normal. At the time of reporting on 30-Oct-2009, the patient's joint pain in ankles and wrists and itchiness and red spots persisted. The patient had many treatments, not specified, to no avail. The reporter felt that there was a reasonable possibility that joint pain in ankles and wrists, itchiness and red spots were caused by the therapy with GARDASIL. Joint pain in ankles and wrists were considered to be disabling as it impeded her everyday life. Joint pain in ankles and wrists, itchiness and red spots were considered as other important medical events by the reporter. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory test, ??/Jan?09, Arthritis test: normal

History:

Prex Illness: Polycystic ovarian syndrome

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **366001-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Sep-2008	01-Sep-2008	0	09-Nov-2009	10-Nov-2009	FR	WAES0911USA00153	10-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ40490	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion

Symptom Text: Information has been received from agency via a Case Line Listing via CSL as part of the business agreement, concerning a 16 year old female with a history of acute reaction to stress who on September 2008 was vaccinated IM with a 0.5 mL third dose of GARDASIL (Batch No. NJ40490). Instantaneously, on September 2008 the patient experienced convulsions gran mal (severe). Subsequently the patient recovered without sequelae from convulsions gran mal (severe). The reporter felt that convulsions gran mal (severe) were "probable" related to therapy with GARDASIL. Convulsions gran mal (severe) were considered other important medical events and required emergency care. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Acute reaction to stress

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **366031-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Oct-2009	27-Oct-2009	6	09-Nov-2009	13-Nov-2009	CA		20-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Complex partial seizures, Cough, Electroencephalogram abnormal, Grand mal convulsion, Lymphocytosis, Upper respiratory tract infection, Viral infection

Symptom Text: Generalized tonic clonic seizure. Final DX; Generalized seizure, resolved, lymnphocytosis, Recent URI Tonic clonic sz <1 min. Short post ictal. All diags neg. Increased lymphocytes, viral illness. Phenergan for recent URI, cough. Neuro PE neg. D/C to home stable. Refer to neuro. Abnormal EEG. Complex partial seizure. MRI ordered. ICD9 Codes: 780.39

Other Meds:

Lab Data: CBC; ct scan; chem panel - negative. Labs & Diags: Lymphocytes 10% (H), EEG - spikes, epileptic in character

History: PMH: intermittent nocturnal incontinence, learning disability Allergies: UNK

Prex Illness: None

Prex Vax Illns:

Vaers Id: **366087-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Aug-2009	21-Aug-2009	0	09-Nov-2009	13-Nov-2009	MD		13-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Feeling abnormal, Pain, Pyrexia

Symptom Text: Patients states that same day of vaccine injection felt "terrible", achy, fever, chills. Client went to ER. Did not call.

Other Meds:

Lab Data:

History:

Prex Illness: none

Prex Vax Illns: Fever, chills~HPV (Gardasil)~1~18.00~Patient

Vaers Id: 366111-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Nov-2008	01-Mar-2009	120	09-Nov-2009	11-Nov-2009	MA		03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Arthralgia, Asthenia, Chest pain, Costochondritis, Decreased appetite, Fatigue, Joint effusion, Joint swelling, Joint warmth, Leukocytoclastic vasculitis, Pruritus, Pyrexia, Rash erythematous, Rash papular, Skin hyperpigmentation, Urticaria, Urticaria chronic, Weight increased

Symptom Text: Developed fevers, joint pains, chronic urticaria. Seen by multiple subspecialists over course of several months. ```12/16/09 MR received from PCP which include multiple consults with final dx: Urticarial Vasculitis. Pt initially began with c/o hives, joint pains/swelling and fevers which began in 2/2009. Chest pain initially thought to be costochondritis. Warmth, tenderness and effusions noted in ankles and wrists. Skin (+) for diffuse blanching erythematous papular rash, some hyperpigmentation. Hives all over with diffuse pruritis. Missed ~25 days of school. Decreased appetite and energy. (+) Anxiety and fatigue. Improvement with steroids with steroid wt gain. Antihistimines not very effective.

Other Meds:

Lab Data: Elevated inflammatory markers, negative auto-antibodies. Further workup included skin biopsy (neutrophilic infiltrate, question of vasculitis), as well as pan-CT (mild lymphadenopathy) and lymph node and bone marrow biopsies to rule out ma

History: ```PMH: T&A, ear infections. allergy to dilaudid./

Prex Illness: No; unsure exact date of vaccination. 2nd dose given January 2009

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **366132-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Oct-2009	29-Oct-2009	0	09-Nov-2009	13-Nov-2009	CA		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	9844P1		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	V3048AA		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head discomfort, Loss of consciousness, Sensory disturbance

Symptom Text: Rush on arm where shot was given all the way to head rush and Black out.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **366187-1** **Related reports:** 366187-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Nov-2009	09-Nov-2009	0	09-Nov-2009	11-Nov-2009	CA		11-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C3250BA	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB342AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1353Y	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3044AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: post vaccination, patient walked to restroom for urine sample to be taken. upon waiting outside of restroom door, patient fainted and hit her head against wall. patient responded quickly and incident occurred for 1-2 minutes

Other Meds:

Lab Data: none

History: none

Prex Illness: right pelvic pain

Prex Vax Illns:

Vaers Id: **366187-2** **Related reports:** 366187-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Nov-2009	09-Nov-2009	0	09-Nov-2009	11-Nov-2009	CA		12-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB342AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3044AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3250BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: fainting

Other Meds: none

Lab Data: none

History: none

Prex Illness: right pelvic pain

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **366259-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Feb-2009	15-May-2009	81	09-Nov-2009	11-Nov-2009	IA		03-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Autoimmune disorder, Joint swelling, Oedema peripheral, Psoriatic arthropathy

Symptom Text: Patient had vaccines on 12/17/2008, 2/23/2009, and 6/23/2009 and began experiencing a swollen finger in 5/2009. This proceeded over the next few months to her finger joints and down her tendon to her wrist. She is diagnosed with psoriatic arthritis because of her inflammation of joint and tendon (tenosynovitis) in her left hand. They want to treat her with methotrexate to attack this auto-immune disorder. 11/23/09 Medical records received for date 5/28/09. DX: left middle finger tenosynovitis. Pt presented w/ c/o left mid. finger swelling, unable to recall any injury. OV 8/4/09 Cont. c/o swelling left mid. finger no extends to palm of hand. Ref. to ortho.

Other Meds: Received tetanus shot and 1st dose of Gardasil on 12/17/2008. Received second dose of Gardasil on 2/23/2009 and third dose on 6/23/2009. Took Advil from May to June to try and decrease swelling of tendon and joint in finger.

Lab Data: MRI shows tenosynovitis, hospital has run many blood tests and x-rays. Visits to 2 orthopedic surgeons, 1 rheumatoid arthritis doctor, and 1 eye surgeon.

History: No

Prex Illness: No

Prex Vax Illns: fainting~HPV (Gardasil)~1~13.58~Patient

Vaers Id: **366298-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Apr-2008	23-Dec-2008	245	10-Nov-2009	12-Nov-2009	GA	WAES0805USA04978	17-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abnormal labour, Blood pressure increased, Blood test, Caesarean section, Chorioamnionitis, Drug exposure during pregnancy, Induced labour, Packed red blood cell transfusion, Postpartum haemorrhage, Pre-eclampsia

Symptom Text: Information has been received from a mother, for the Pregnancy Registry for GARDASIL, concerning her daughter, a 17 year old female with a history of antibiotic therapy and no known drug reactions/allergies, who on 22-APR-2008 was vaccinated (route unknown) with a 0.5 mL first dose of GARDASIL (Lot # unknown). Concomitant therapy included (BACTRIM, also reported as "Bectrum"). The mother reported the pregnancy for her daughter. The patient was administered with the first dose on 22-APR-2008 and as of 3-May-2008 she is 5 weeks pregnant (LMP "March 2008"). The lot # is not provided. No AE involved. A blood test was performed. Unspecified medical attention was sought. No product quality complaint was involved. Follow up information was received from the nurse who indicated that on approximately 23-DEC-2008 the patient had an induction of labor after she came into the office with some contractions and elevated blood pressure (bp). During the induction the patient "quit dilating" and at 38 +2/7 weeks had a Cesarean section. On 23-DEC-2008 the patient delivered a normal baby, with Apgars values of 8 and 9 at 1 and 5 minutes respectively and only required a bulb syringe suctioning, "but no further resuscitation", the nurse also reported "everything looked good" with the baby. The patient also had a postpartum hemorrhage, and was transfused two units of packed red blood cells. Post-operatively the diagnosis was pre-eclampsia and chorioamnionitis. She also received antibiotics (unspecified) for the chorioamnionitis. The nurse also reported that the baby had a sepsis workup due to the mother's chorioamnionitis, but he was asymptomatic and all of his laboratory tests were normal also. The baby was discharged home with his mother on 26-DEC-2008. At the time of the report, the outcome of the patient was unknown. Upon internal review pre-eclampsia, chorioamnionitis and patient quit dilating and having a C section were considered as other important medical event. Additional information is not expected.

Other Meds: BACTRIM

Lab Data: diagnostic laboratory, pregnant

History: Antibiotic therapy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **366311-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	29-Sep-2009	01-Oct-2009	2	10-Nov-2009	12-Nov-2009	FR	WAES0911USA00475	12-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ02700		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blood test, Lumbar puncture, Meningitis

Symptom Text: Information has been received from a health authority (HA ref DK-DKMA-200903470). It was reported that a 20 year old female patient (weight 55kg, height 170 cm), on 29-SEP-2009 was vaccinated with a dose of GARDASIL (lot# NJ02700, batch NK02460), intramuscularly. On 01-OCT-2009, the patient developed meningitis. It was reported that the patient was hospitalized (date and duration not reported), blood samples were taken (not further specified) and lumbar puncture was done (not further specified. It was reported that the patient recovered on 16-OCT-2009. The patient received no concomitant medications and had no concurrent illness. Other business partner number included E2009-10181. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **366346-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	02-Sep-2009	05-Sep-2009	3	10-Nov-2009	12-Nov-2009	FL		22-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0313Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Fatigue, Muscular weakness, Pain

Symptom Text: BODY ACHES, MUSCLE WEAKNESS. FIRST THREE WEEKS FATIGUE, DIFFICULTY BREATHING SPECIALLY WHEN TALKING FOR MORE THAN 20 MINUTES. 11/13/09 Medical records received for dates 9/2/09 to 11/10/09. OV 9/2 received gardasil vax dose 1. OV 9/10 wellness exam visit pap WNL. OV 10/9 pt c/o body aches, muscle pain, dizziness, SOB. DX: fatigue, dyspnea, impacted cerumen. OV 10/13 c/o SOB, allergies, fatigue. Referral given cardio/pulm eval. 11/9 pt called MD stated left side muscle weakness where gardasil vax given, difficulty breathing. 11/10 pt called MD stated sx resolved. Declined further gardasil vax.

Other Meds:

Lab Data: DOCTORS CAN'T FIND ANYTHING UNUSUAL IN BLOOD TESTING, BUT I WAS REFERRED TO A PULMONOLOGIST AND I'M CURRENTLY DOING SOME MORE TESTING. 11/13/09 Medical records received for dates 9/2/09 to 11/10/09 Diagnostics/Labs: EKG(-), CXR(-), CBC WNL

History: ALLERGIES(DUST, MOLD, CATS) 11/13/09 Medical records received for dates 9/2/09 to 11/10/09 PMH: Anemia, HSV1

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **366492-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Nov-2009	04-Nov-2009	1	10-Nov-2009	13-Nov-2009	OR		13-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB287A	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1049Y	1	Right arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2727AA	0	Left arm	Subcutaneously	
TDAP	UNKNOWN MANUFACTURER	UF544AA		Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0311Y	0	Right arm	Intramuscular	
FLU	SANOFI PASTEUR	UT3175AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site streaking, Injection site warmth

Symptom Text: Mom called the office at 10:38 am on 11/4/09 - stating childs rt arm, subq area was red & w/streak going up arm. Warm to touch - measured 6x2 cm - cool packs - observe.

Other Meds: Ibuprofen - prn

Lab Data: Lot #1049Y - right arm -sc reaction to: VARICELLA virus vaccine. 1 - previous dose.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **366512-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	10-Nov-2009	10-Nov-2009	0	10-Nov-2009	13-Nov-2009	AZ		13-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Unknown	Intramuscular	
	FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	1008143P	0	Unknown	Intramuscular	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	98438P1	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Syncope

Symptom Text: Fainting episode after administration of GARDASIL shot - associated with jerky muscle movement.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **366527-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	30-Oct-2009	30-Oct-2009	0	10-Nov-2009	11-Nov-2009	KS		12-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL	2	Right arm	Unknown	
MNC	WYETH PHARMACEUTICALS, INC	NULL	1	Left arm	Unknown	
TDAP	SANOFI PASTEUR	NULL	1	Right arm	Unknown	
VARCEL	MERCK & CO. INC.	NULL	2	Left arm	Unknown	
HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor

Symptom Text: vaccine administered, patient left immunization room and was asked if she had any signs or symtoms related to vaccine replied "No" steped into hallway with family and started to feel faint. Patient was taken back to room elvated feet, Bp taken, given Juice and Crackers, patient facial skin was pale and sweating. She was not released to go home until all symptoms subsided and able to walk with out assistance.

Other Meds:

Lab Data:

History: none

Prex Illness: no illness at time

Prex Vax Illns:

Vaers Id: **366554-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Aug-2009	13-Oct-2009	48	10-Nov-2009	11-Nov-2009	NH		12-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	03124	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: no pmh of headaches. started having headaches daily, every evening, through today (11/10/09). normal bp & neuro exam.

Other Meds: none on vaccine date; ibuprofen bid since headache onset

Lab Data: bp 94/56

History: constipation, allergic rhinitis

Prex Illness: constipation

Prex Vax Illns:

Vaers Id: **366658-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Oct-2009	26-Oct-2009	0	11-Nov-2009	13-Nov-2009	OH		13-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: Received 2nd GARDASIL injection 10/26/2009. After injection reported headache & dizziness. Examined & observed by Dr. Given Tylenol & went home in stable condition.

Other Meds: Tylenol

Lab Data:

History: NKA

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **366861-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2009	01-Jun-2009	0	12-Nov-2009	13-Nov-2009	FR	WAES0911PHL00003	04-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Intra-uterine death, Menstruation delayed

Symptom Text: Information has been received from a physician concerning a female who in approximately June 2009, was vaccinated with first dose of GARDASIL. Second dose was received on approximately August 2009. Subsequently, the patient had delayed menstrual period and was confirmed to be pregnant through ultrasound on approximately October 2009. It was also through the ultrasound that it was found out that the patient had conjoined twins. The patient requested for a second sonogram by a different sonologist on approximately October 2009 and it was during the second laboratory test that it was found that the conjoined twins were already dead. The patient is set to continue with her third dose which is scheduled on 10-NOV-2009. Upon internal medical review, intra-uterine death was considered to be an important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, ??Oct?09, pregnant with conjoined twins; ultrasound, ??Oct?09, fetal death

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **366866-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Oct-2009	09-Oct-2009	0	12-Nov-2009	13-Nov-2009	FR	WAES0911USA01184	13-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0773X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Clonus, Dizziness, Gaze palsy, Headache, Malaise, Myalgia, Pyrexia, Syncope

Symptom Text: Case received from a health care professional on 30-OCT-2009 and transmitted by a distributor, under the reference SPV09009. An 18 year old female patient with no relevant medical history had received the first dose of GARDASIL (lot number 0773X, batch number NK19190) via intramuscular route on 09-OCT-2009. One minute after vaccination, she experienced dizziness, a fainting episode, mild clonic movements and eye rolling back. These initial symptoms lasted approximately 10 minutes. Then the patient experienced headache, myalgia, joint pain, fever and malaise. The symptoms lasted 72 hours. The patient was treated with acetaminophen (dose unknown). The patient was not hospitalized nor was she referred for any further testing. In addition, she refused to complete the vaccination schedule with this vaccine. She was not receiving any concomitant medication at the time of the event. At the time of reporting, the patient had fully recovered and was monitored by the reporting physician. She was currently in good health. Dizziness, fainting, clonic movements, eye rolling, headache, myalgia, joint pain, fever and malaise were considered to be other important medical events. No further information expected. Other business partner numbers include E2009-10288.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **366869-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	06-Dec-2007	31-Jan-2008	56	12-Nov-2009	13-Nov-2009	FR	WAES0911USA01197	13-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myelitis, Visual impairment

Symptom Text: Case received from the Health Authority in a foreign country on 02-NOV-2009 under the reference number PEI2009023367. It was reported that a 19-year-old previously healthy female patient was vaccinated with a first dose of GARDASIL on 27-SEP-2007, with a second dose of GARDASIL on 06-DEC-2007 and with a booster dose of TD-IPV (manufacturer unknown) on 21-JAN-2008. Lot #, injection sites and routes were not reported. At the end of January 2008 the patient developed visual disturbances and at the end of March-2008 she experienced myelitis. Laboratory values were positive for oliclonal bands in CSF. The patient recovered completely within unspecified time. The events were reported to be other important medical event. Other business partner numbers include E2009-10183. No further information is available. File closed.

Other Meds: Unknown

Lab Data: CSF oligoclonal band profile, ??08, Positive

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **366873-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Nov-2008	13-Nov-2008	2	12-Nov-2009	13-Nov-2009	FR	WAES0911USA01319	13-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain lower, Papilloma viral infection, Vulvovaginal human papilloma virus infection

Symptom Text: Health Authority (HA ref. DK-DKMA-20093032) concerning an 18 year old female patient with no concurrent illness who on 11-NOV-2008 was vaccinated with the first dose of GARDASIL (lot#, Batch # and site of administration not reported) IM. There was no concomitant medication. On 13-NOV-2008, the patient developed lower abdominal pain. The patient was hospitalized (not further specified) and laparoscopy revealed no abnormalities. On 20-DEC-2008, the patient developed vulvovaginal condyloma. The patient received laser therapy treatment (not further specified). Biopsy of portio uteri and cervical canal was normal. Biopsy of vulva revealed condyloma, HPV type 6 and 82. It was reported that the patient had not recovered. Other business partner number included: E2009-10326. Additional information has been requested.

Other Meds: None

Lab Data: laparoscopy, 13Nov08, normal; vulvar biopsy, 20?Dec08, condyloma, HPV type 6 and 82; uterine biopsy, 20?Dec08, normal; cervix biopsy, 20?Dec08, normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **366877-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-Nov-2009	13-Nov-2009	MA	WAES0911USA00519	13-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Heart rate irregular, Muscle spasms, Myalgia, Nausea, Rash, Syncope, Wheelchair user

Symptom Text: Information has been received from a physician who reported that a mother chose to stop her daughter's GARDASIL due to "bad press". The article was in newspaper on 29-OCT-2009 concerning three girls, known as the "GARDASIL Girls" had experiences after receiving the vaccine. On an unspecified date the patient who was vaccinated with a dose of GARDASIL (lot # not reported). On an unspecified date she experienced charley horse, spasms and pain in muscles with fainting, nausea, irregular heartbeat and rash since she received GARDASIL. Now she was using a wheelchair. The patient's outcome was not reported. Upon internal review, using wheelchair was considered to be disabling. This is one of three reports from the same source. No additional information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **366879-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	23-Mar-2009	10-May-2009	48	12-Nov-2009	13-Nov-2009	FR	WAES0911USA01321	25-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0779X	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Condition aggravated, Eyelid oedema, Nephrotic syndrome, Oedema peripheral, Proteinuria

Symptom Text: Information has been received from an Health Authority (case# 105548) through (local case# IT468/09) concerning a 10 year old female patient with nephrotic syndrome who on 23-MAR-2009 was vaccinated with the first dose of GARDASIL (lot# 0779X, batch # NJ36070) IM. Concomitant therapy included deltacortene and ZYRTEC. On 10-MAY-2009 the patient presented with edema of the lower limbs and below the eyelids, asthenia and proteinuria. The patient was admitted in day hospital and her deltacortene dosage was increased. At the time of reporting, the patient's condition had improved. The final outcome was not reported. Other business partner number included: E200910294. The case is closed. Additional information has been requested.

Other Meds: ZYRTEC

Lab Data: Unknown

History:

Prex Illness: Nephrotic syndrome

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **366880-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	22-Aug-2009	17-Sep-2009	26	12-Nov-2009	13-Nov-2009	FR	WAES0911POL00003	13-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Herpes virus infection, Rash erythematous, Swelling, Urticaria

Symptom Text: Information has been received from a physician concerning a 20 year old female who on 22-AUG-2009 was vaccinated with the first dose of GARDASIL. On 17-SEP-2009 the patient experienced herpes, body swelling and whole body with red spots (acute urticaria) and was hospitalized. The patient was discharged from the hospital. The discharged diagnosis was acute urticaria. The patient's herpes and body swelling and whole body with red spots (acute urticaria) persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **366928-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Jan-2009	27-Jan-2009	0	12-Nov-2009	12-Nov-2009	TX		20-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Antibiotic therapy, Asthenia, Breast swelling, Chest pain, Dizziness, Erythema, Fall, Fatigue, Feeling hot, Gait disturbance, Hypoaesthesia, Loss of consciousness, Pain, Paraesthesia, Syncope, Tenderness

Symptom Text: Initially after the vaccination Jasmyne felt hot and passed out. She was woozy and we waited until she was more stable so we could take her home. Within a week roughly she started to have random fainting spells which she had never experienced before. Additionally, she has numbness/tingling in arms and legs and intermittent chest pains. She is constantly fatigued and because we never know when she will have a fainting episode she is homeschooled. She tends to be very weak and dizzy after she faints and it can take a hour or so for her to regain any strength. Many times her legs give out when she is walking and she falls down. She has seen multiple doctors and specialists. We just monitor her condition and make sure stay hydrated and we also increased her sodium to try and combat the fainting which has been slightly effective. The biggest issue now is the constant fatigue and pain she experiences regularly. 11/16/09 Medical records received fro DOS 1/27/09. PCP notes documents vaccine dates and h/o beast pain, redenss, swelling. ABx therapy.

Other Meds:

Lab Data: Multiple blood tests, cardiac stress tests, EEG, MRIs, & general physical exams.

History: h/o beast pain, redenss, swelling.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **366980-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	10-Nov-2009	10-Nov-2009	0	12-Nov-2009	13-Nov-2009	TX	TX090074	20-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB140AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1353Y	0	Right arm	Unknown	
	MMR	UNKNOWN MANUFACTURER	0777Y	0	Left arm	Unknown	
	FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	10127604	0	Left arm	Unknown	
	TD	UNKNOWN MANUFACTURER	A027A	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Synacope, 9:45 AM

Other Meds: NONE

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **367044-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Nov-2007	16-Nov-2007	7	12-Nov-2009	23-Nov-2009	CA		30-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2351AA	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	00126	1	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2609AA	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Asthenia, Ataxia, Dyspnoea, Dysuria, Fatigue, Headache, Hot flush, Malaise, Syncope, Vertigo

Symptom Text: 11/16/2007 approx. 1:30 p.m. Fri at school admin principal called. Pt was feeling very ill. Could not walk and feeling body weak. Unable to express herself went to ER. Blood work, CT scan EGD test. On 11/18/2007 went back to ER Hosp. Referred to Neurologist w/meds. 12/04/09 ED records received for DOS 11/16/09. Pt. brought to ED after fainting at school, feeling very tired; c/o shortness of breath, painful urination. Discharged home. DX: ataxia vs. pseudoataxia 12/04/09 ED records received for DOS 11/18/09. Pt presents with vertigo, headache, hot flashes, "legs not cooperating". Discharged home.

Other Meds:

Lab Data: Blood Labs CT Scan; ECG test; EMG test; Pelvic test. Eye test; head; neck; back MRI. Done twice. 3 Neurologist MD (seen) meds. 12/04/09 Labs/Diagnostics:CT brain scan : no evidence of acute intracranial pathology; AST 10 (L); ALT 28 (L);

History: 12/04/09 PMH: ADHD; NKDA; scoliosis; anxiety attack

Prex Illness: Vaccines was painful at time

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367096-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Oct-2009	14-Oct-2009	2	13-Nov-2009	16-Nov-2009	WI		16-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U3193AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0313Y	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0972Y	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Oedema peripheral, Rash

Symptom Text: Hypersensitivity rash 3 days after immunizations. Hand swelling.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367107-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Nov-2009	11-Nov-2009	0	13-Nov-2009	16-Nov-2009	FL		16-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0131Y	0	Right arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB351BA	0	Left arm	Unknown	
FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	1008133P	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Patient given their vaccinations. Pt left exam room and when reached front of clinic, felt faint, no LOC, no vomiting. Vital signs initially HR 64, pulse ox 100%, BP 100/62. Pt seated, given blow by O2 and status improved.

Other Meds:

Lab Data: None

History: None

Prex Illness: Stye

Prex Vax Illns:

Vaers Id: **367225-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Nov-2009	10-Nov-2009	0	13-Nov-2009	16-Nov-2009	TX		17-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U3202AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1497X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Nausea, Vomiting

Symptom Text: After shots client became flush and c/o nausea. Client then vomited while sitting in chair. Cold compress to forehead v/s normal. B/P 100/70 after sitting for 20 more minutes client states still feeling fine and no nausea. Client states she ate a very greasy hamburger earlier, but feels fine now. Denies any s/s of light headness or nausea. Told mother to take number to call and let them know how she is feeling and explained to mom to take her to doctor or ER if any more s/s occur.

Other Meds: None

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **367228-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	11-Nov-2009	11-Nov-2009	0	13-Nov-2009	17-Nov-2009	MA		24-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Gluteous maxima	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Drug administered at inappropriate site, Injection site haematoma, Injection site pain, Myalgia, Pain in extremity

Symptom Text: received 2nd round of shot in lower back/buttock at 4 PM and around 5 PM started having extreme muscle pain at injection site. Later that night, i felt like i could not move without extreme muscle pain. Today 11/13/09 i feel muscle pain is at it's worst with muscle pain up and down my entire back with bruising at injection site. - same problem during 1st round of shot, but injection was put in right arm. later that day pain spread from injection site in arm to entire arm down to wrist to under arm and side by the 4th day. 5th day finally had relief.

Other Meds:

Lab Data: none

History: no

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367259-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Oct-2009	22-Oct-2009	0	13-Nov-2009	16-Nov-2009	ND	ND0913	17-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Right arm	Intramuscular	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500763P	0	Unknown	Unknown	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	98448P1	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor

Symptom Text: BECAME PALE AND LIGHT HEADED WITHIN 10 MINUTES OF ADMINISTERING VACCINE. LAID DOWN ON FLOOR WITH COOL COMPRESS TO FOREHEAD. MOTHER PRESENT.

Other Meds: NA

Lab Data: NA

History: PENICILLIN AND SULFA

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367323-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Nov-2009	13-Nov-2009	0	13-Nov-2009	17-Nov-2009	GA		24-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Pain at injection site. Complained they felt like they had an allergic reaction due to the pain.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367336-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Oct-2009	12-Nov-2009	28	13-Nov-2009	16-Nov-2009	CA		07-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500759P	0	Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3021AA	0	Left arm	Unknown	
TDAP	SANOFI PASTEUR	UF499AA	5	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0990Y	1	Left arm	Subcutaneously	
FLU	SANOFI PASTEUR	U3171BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Cough, Gait disturbance, Headache, Influenza like illness, Oedema peripheral, Pyrexia, Tenderness, Vomiting

Symptom Text: Fever, cough x 3d, vomiting x 1d poss influenza. 11/17 and 11/30 Medical records received for DOS 11/13/09-11/14/09. Final DX: Acute febrile illness in child, influenza like symptoms Diff walking, bil LE edema x 4days, fever. vomiting, HA, myalgia, cough. On PE no edema noted, bil calf muscle tenderness. Gradually resolving. D/C to home in good condition.

Other Meds: Tamiflu/Tylenol-11/13/2009

Lab Data: cbc, cmp, influenza a/b, esr, ua cx Labs & Diags: UA WNL, CXR neg. FLu tests neg.

History: costochondritis-6/4/09, 6/11/09 Allergies: nka

Prex Illness: amenorrhea, 2nd degree-10/15/09 costochondritis-6/4/09, 6/11/09

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367391-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	09-Oct-2009	10-Oct-2009	1	14-Nov-2009	17-Nov-2009	OH		24-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstrual disorder, Pain

Symptom Text: The first adverse event I assume has to do with Gardasil. My periods usually last 3-4 days and my last 2 periods since receiving the vaccine have lasted up to 10 days. I am currently on day 9 with no signs of an end. I have also been experiencing pain in my left arm and shoulder and have not been hurt there by being hit or falling or otherwise. The pain is from my elbow up to my shoulder and hurts worse on my shoulder and near where my shoulder bone and clavical bone touch. I am calling my doctor on Monday to report these effects as well.

Other Meds: Minocycline and Aczone

Lab Data:

History: I have hydradentitis Supprativa. I was on Minocycline and Aczone at the time of the injection.

Prex Illness: No.

Prex Vax Illns: MENSES LASTING LONGER THAN USUAL~HPV (Gardasil)~1~25.83~Patient|PAIN IN LEFT ARM~HPV (Gardasil)~1~25.92~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367423-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	11-Nov-2009	13-Nov-2009	2	15-Nov-2009	18-Nov-2009	WY		26-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	9525U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysphagia, Dyspnoea, Headache, Muscle twitching, Palpitations, Pharyngeal oedema, Sinus headache, Sinusitis, Swollen tongue

Symptom Text: Twitching in back of legs, throat swelling, heart palpitations, difficulty swallowing, difficulty breathing, swelling of tongue 12/02/09 Medical record received for DOS 11/11/09. Presented with headache, sinus pressure x 3 weeks; requesting second gardasil injection. DX: Acute bacterial sinusitis ```01/07/10 and 01/13/10 PCP records received for DOS 8/31/09. Pt presents for thyroid check and requesting first gardasil vaccine ```1/13/09 Primary care record received for date of service 8/31/09: Presents for thyroid check and Guardasil injection.

Other Meds: Azithromyacin

Lab Data:

History: Hypothyroidism; 12/1/09 PMH: NKDA; hypothroid

Prex Illness: Sinus infections symptoms present

Prex Vax Illns:

Vaers Id: **367604-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Jun-2008	20-Feb-2009	247	16-Nov-2009	18-Nov-2009	CA		24-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	3	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal discomfort, Acne, Arthropod bite, Asthenia, Convulsion, Dizziness, Headache, Hyperhidrosis, Hypersomnia, Sleep disorder

Symptom Text: seizure, headache,dizziness, weakness, stomach discomfort 12/17/09 clinic records received for DOS 07/31/07and 6/18/08 and vaccination list record received for DOS 12/09/1993 thr 06/18/2008. DX: Well Adolescent Care, Acne 07/31/07 office note docu. sports physical with unlimited participation. 06/18/08 office note notes c/o not sleeping well and insect bite X 1wk. Parent concerned about excessive sleep and sweats alot. Acne on face and upper back. Prescriptions given:clindamycin phosphate 1% TOP, benzoyl peroxide 6% TOP and differin 0.1% TOP. Vaccination rec reflect patient received HPV on 07/31/07, 10/09/07 and 06/18/08.

Other Meds:

Lab Data:

History: none

Prex Illness: felt weak,nausea,dizzy,passing out

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367663-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	12-Nov-2009	15-Nov-2009	3	16-Nov-2009	19-Nov-2009	MN		19-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: rash arm, chest, upper back

Other Meds:

Lab Data:

History: denies

Prex Illness: denies

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367696-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jun-2009	16-Jun-2009	0	16-Nov-2009	17-Nov-2009	FR	WAES0911USA01196	17-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Convulsion, Dizziness, Fall, Fatigue, Headache, Nausea, Syncope

Symptom Text: Initial case was reported on 04-Nov-2009 by a health agency (HA ref. DK-DKMA-20092893). Upon internal review, the case was upgraded to serious as the patient was hospitalized and convulsion was considered a medically significant event. It was reported that a 14 year old female patient was vaccinated with a dose of GARDASIL (i.m. batch number and site of administration not reported) on 16-Jun-2009 at 14:40. Ten minutes post vaccination, the patient experienced dizziness and headache. Twenty minutes post vaccination the patient collapsed (reported as falling by reporter) and experienced 1 minute of convulsions. Since the episode of convulsions, the patient experienced nausea and tiredness. It was reported that dizziness lasted for 70 minutes and that the patient recovered from all other symptoms on 16-Jun-2009. The patient suffered from amnesia of the falling and convulsion episode. It was reported that the patient had not recovered from amnesia. The patient was hospitalized due to the convulsion episode (no dates reported). It was reported that objective examination was normal (not further specified). No blood samples were taken. The patient received no concomitant medicine. Other business partner's numbers included: E2009-10287.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **367710-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Nov-2009	06-Nov-2009	0	16-Nov-2009	18-Nov-2009	TX		18-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injection site erythema, Injection site pain, Injection site swelling, Local reaction, Musculoskeletal pain, Paraesthesia

Symptom Text: 24 hours after receiving the injection the patient complained of numbness in her left arm - the pain radiated to shoulder-the area did ha a local reaction area was red and swollen. She also complained of numbness and tingling in her fingertips.

Other Meds: None

Lab Data:

History: none

Prex Illness:

Prex Vax Illns:

Vaers Id: 367711-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	09-Oct-2008	01-Feb-2009	115	16-Nov-2009	17-Nov-2009	NY	WAES0911USA01240	17-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL concerning a 22 year old female who was vaccinated intramuscularly with the first 0.5 dose of GARDASIL in the left upper arm in August 2008 during her first month of pregnancy, reported in (WAES # 0809USA00445) the second dose of GARDASIL in her right upper arm in October 2008 with no other vaccines was given on this date and the third dose of vaccine on her left arm on 04-NOV-2009. Concomitant therapy included 250 mg FLAGYL for bacterial vaginosis infection and folic acid 3 weeks after the visit and the flu vaccine in her right arm. The patient delivered a male child by caesarean section due to gastroschisis 3 months ago. Child had complication gastroschisis, abdominal defect, which required surgery and a longer stay at the hospital after birth. child was being seen by specialist. Follow up information was received from the physician concerning the patient with no obstetric history as well as no medical history or concurrent conditions who was vaccinated with her first, second and third dose of GARDASIL on 05-AUG-2008, 09-OCT-2008 and 04-OCT-2009 respectively. Concomitant therapy included FLAGYL, folic acid from 07-AUG-2008 and influenza virus vaccine on 01-NOV-2008. Amniocentesis indicated that the patient had 4.5 months pregnancy (LMP: 12-AUG-2008; RDD: 19-MAY-2009). On 12-AUG-2009, at 35 weeks of gestation, the patient delivered a abnormal male baby weighting 4 pounds, 18 cm in length with head circumference of 35. The baby was born with gastroschisis. There were no complications or abnormalities for the baby. The mother had not complication during pregnancy and had complication during labor/delivery. The mother did not experienced any infections or illnesses during pregnancy. Amniocentesis indicated that the patient was at 4.5 months gestation. Other medication used during this pregnancy included. Follow up information was received from the physician via telephone on 09-NOV-2009 concerning the patient received the second p

Other Meds: Unknown

Lab Data: amniocentesis, 4.5 months pregnancy; serum beta-human, 09/02/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367715-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Oct-2009	08-Oct-2009	0	16-Nov-2009	17-Nov-2009	NE		18-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B047	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3048AA	1	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB32	1	Left arm	Intramuscular	
	FLU(H1N1)	UNKNOWN MANUFACTURER	500762P		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0313Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Headache, Syncope

Symptom Text: Pt apparently fainted following her vaccinations striking the back of her head on the uncarpeted floor. Complained of headache. Was transported by ambulance to ER.

Other Meds:

Lab Data: CT scan

History:

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367731-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Sep-2009	28-Oct-2009	30	16-Nov-2009	18-Nov-2009	PA		30-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	02494	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Nov-2009	10-Nov-2009	0	16-Nov-2009	18-Nov-2009	FL		18-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0912Y		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1332Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Visual impairment

Symptom Text: Felt light headed, saw spots, laid down passed out.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **367823-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Nov-2009	04-Nov-2009	1	16-Nov-2009	17-Nov-2009	FL		01-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500761P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy, Facial paresis, Tinnitus

Symptom Text: (Bells Palsy) 11/4/09 left facial palsy - weakness left eyelid, nose mouth on left side, ringing left ear began 24 hours after vaccine. Treated 11/01 with ZITHROMAX administered for strep throat, appeared resolved 11/3/09. 11/20/09 Medical records received for DOS 11/03/09- 11/13/09. Final DX: Bell's Palsy Facial weakness s/p flu nasal mist vaccine and Gardasil #1. Buzzing in L ear. L eye not closed, weakness mouth and nasal L side. DX strep throat 2 days prior to vaccine.

Other Meds: ZITHROMAX

Lab Data:

History: None Allergies: NKA

Prex Illness: Strep throat resolving

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367899-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	18-May-2009	18-May-2009	0	16-Nov-2009	18-Nov-2009	NM		18-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pain

Symptom Text: Patient reported onset of headache same day vaccine (Gardasil) #1 was given. Pain lasted for one week, was relieved by taking OTC acetaminophen.

Other Meds: Ortho Evra Patch, Levoxyl.

Lab Data:

History: Hypothyroidsm.

Prex Illness: None reported

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367982-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Nov-2009	14-Nov-2009	0	17-Nov-2009	19-Nov-2009	CO		19-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Fall, Head injury, Loss of consciousness, Muscle rigidity

Symptom Text: Patient jerked backwards, went rigid and fell straight back on her head on a concrete carpeted floor. Patient lost conciousness for a few seconds, and regained orientation thereafter. She was given orange juice, and laid on her back. Paramedics were present and assessed her head injury and transported the patient to the nearby Hospital.

Other Meds:

Lab Data: Pt's blood pressure was low when assessed after reaction, and patient never gained full color after syncope.

History: NONE Identified

Prex Illness: NONE Identified

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **367999-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Nov-2009	12-Nov-2009	1	17-Nov-2009	19-Nov-2009	NC		19-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site rash

Symptom Text: about 12 hours after vaccine administration patient c/o red raised rash in approximately 3 in" area around injection site. BEANDRYL administered by patients mother.

Other Meds: Nuva Ring -contraception

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **368003-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Dec-2008	04-Dec-2008	0	17-Nov-2009	18-Nov-2009	WV	WAES0812USA01628	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse, for the pregnancy registry of GARDASIL concerning a 17 year old female patient with no pertinent medical history and no drug reactions or allergic reactions, who on 04-DEC-2008 was vaccinated with the first dose of GARDASIL (lot number not provided) 0.5ml intramuscularly. There was not concomitant medication. Nurse reported that the patient was pregnant. Patient sought unspecified medical attention. No adverse effects reported. Follow up information was received from an obstetrician concerning a female patient with no pertinent medical history and no known drug allergies/drug reactions who on 04-DEC-2008 was vaccinated with the first dose of GARDASIL (Lot # not provided). It was reported that there were no complications, infections or illnesses during pregnancy. On 11-JUL-2009 the patient delivered a normal male baby (ID # 40105, weight 6 pounds and 14 ounces, length 19.5"). The patient was 40 weeks from her last menstrual period. There were no congenital anomalies or other complications. abnormalities. Follow-up information has been received via pediatric medical records from a physician concerning the patient's baby with passive smoke risk. It was reported that on 13-JUL-2009, at the age of 3 days, the baby underwent an ultrasound test in order to investigate a scrotal mass. On 13-Jul-2009 the following test results were obtained: blood lymphocyte count 25.0 %, blood segmented neutrophil count 65.0%; blood band neutrophil count 4%, slight anisocyte observation, slight poikilocyte observation, slight polychromatic erythrocyte observation, slight macrocyte observation. On 14-JUL-2009, the ultrasound revealed moderate right sided hydrocele. The baby's testicles appear to be normal with the right testicle measuring 1cm and the left testicle 9mm. Arterial flow was noted in both testicles. On 20-JUL-2009, the patient had a newborn exam which showed that the child was a little underweight at that time. The baby's weight was 5.13 lb and his height was 20 in

Other Meds: Unknown

Lab Data: ultrasound, 07/13/09, moderate right sided hydrocele; lymphocyte count, 07/13/09, 25.0%, low; segmented neutrophil, 07/13/09, 65.0%, high; band neutrophil count, 07/13/09, 4%, 10 - 18; anisocyte, 07/13/09, slight; poikilocyte, 07/13/09, sli

History:

Prex Illness: Pregnancy NOS (LMP = 10/01/2008) Passive smoking

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **368008-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	14-Oct-2009	Unknown		17-Nov-2009	19-Nov-2009	WA		02-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Cervical dysplasia, Myalgia

Symptom Text: Joint and muscle pain in lower extremities since first shot given (per pt report) - pt has seen her PCP for workup. ```2/12/10 OB/GYN Records received for dates of service 6/15/09 to 10/14/09. Dx: LGSIL. G0P0 presents for repeat pap smear after colposcopy was done 3/09 for a pap with LGSIL ```2/24/10 OB/GYN records received for dates of service 10/14/09 to 11/10/09. Pt. called office to c/o of joint and muscle pain that she has been experiencing since first HPV vaccine. She has been going for accupuncture which affords only temporary relief. Being worked up by PCP for Sx. ```3/1/10 PCP Records received for date of service 11/11/09. Dx: Gardasil reaction? C/o joint and muscle pain.

Other Meds: Nuvaring

Lab Data: ```3/1/10 PCP Records received for date of service 11/11/09. Labs and diagnostics: CRP 0.6 (WNL). CMP and CBC with Diff WNL.

History:

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **368015-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Nov-2009	11-Nov-2009	6	17-Nov-2009	19-Nov-2009	NY		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	90249Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Blood glucose normal, Fatigue, Hypersomnia, Influenza, Menarche, Nervous system disorder, Speech disorder, Staring

Symptom Text: Started flu sx evening 11/6 (presumed H1N1). Took Ibuprofen only. On 11/11 had staring spell, became nonverbal. Ambulance got normal glucose. Slowly improved over 2 hr in ER. Diagnosed "fatigue, 1st menses" I think this was a CNS symptom of influenza. Seen in office 11/12 normal neurological exam. Phone next day still sleeping a lot. Improving at date of report. Update: Pt hospitalized 11/15 - 17/09 for altered mental status. Extensive work up [EEG, LP, MRI, CT, Viral titers and PCR's] failed to identify a cause. As of today she is definitely improved.

Other Meds: No; Differin topical started that day

Lab Data: In ER: normal BMP; CBC; HCG; Mono spot; drug screen.

History: No

Prex Illness: No; sister had flu 11/5/09

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **368020-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2009	18-Nov-2009	--	WAES0911USA01430	18-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician via a literature article, concerning a pregnant female who on an unknown date was vaccinated with the first dose of GARDASIL. The patient had a spontaneous abortion which occurred 47 days after vaccination with the first dose of GARDASIL. This report was part of a post-marketing surveillance program. The primary investigator felt that spontaneous abortion was possible related to the study therapy. Upon internal review spontaneous abortion was considered to be an other important medical event. This is one of several reports from the same source. No further information is available. A copy of the published article is attached as further documentation of the patient's experience.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **368027-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Sep-2009	24-Sep-2009	0	17-Nov-2009	18-Nov-2009	FR	WAES0911USA02119	18-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Pallor, Syncope, Unresponsive to stimuli

Symptom Text: It was reported that a 12-year-old girl was vaccinated with GARDASIL (parenteral route, first dose) on 24-SEP-2009. Health Authority coded convulsion, syncope, pallor of skin and pallor facial (causalities possible) with onset immediate after vaccination. It was reported that the girl was not able to contact during the syncope which lasted for about 40 seconds. When she woke up, she was pale in the face for 15 minutes. The girl had previously had a similar attack (not further specified) once in school. The nurse advised her mother to get in contact with a doctor for further investigations. She also clearly said that there no signs of anaphylaxis. Form this description, the Health Authority reported that the reaction could possible be a vasovagal reaction. Since the patient had experienced a similar reaction before, the Health Authority also suggested further investigation to exclude possibly underlying neurological disease. The result of this investigation should be known before dose 2 of GARDASIL was given. The outcome was recovered. The events were reported to be other important medical event. Other business partner numbers include E2009-10364. No further information is available. Case is closed.

Other Meds: unknown

Lab Data: Unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **368034-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	06-Nov-2007	08-Nov-2007	2	17-Nov-2009	18-Nov-2009	PA	WAES0911USA00295	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2429AA	0	Right leg	Intramuscular	
	HPV4	MERCK & CO. INC.	1265U	1	Left leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Haematuria, Henoch-Schonlein purpura nephritis, Influenza, Kidney infection, Myalgia, Oedema peripheral, Pain in extremity, Pyrexia, Rash generalised, Rash macular, Staphylococcal infection, Streptococcal infection

Symptom Text: Information has been received from a health professional concerning an 11 year old female student with high blood pressure, an allergy to amoxicillin (hives) and no illness at the time of vaccination who on 20-AUG-2007, was vaccinated intramuscularly with the first dose of GARDASIL (lot# 658556/1060U) into the left thigh. On 06-NOV-2007, the patient was vaccinated intramuscularly with the second dose of GARDASIL (lot# 65435/1265U) into the left thigh and with a first dose of MENACTRA (lot# U2429AA), IM into the right thigh. Concomitant therapy included VASOTEC for blood pressure. On 15-NOV-2007 it was reported that the patient developed rash over her body which started on 08-NOV-2007 (2 days after the second dose of GARDASIL and MENACTRA). A rapid Strep test was performed in the office and was negative. On 16-NOV-2009, she then had a slight growth of Staph A. She was seen again and her feet were hurting, and her left foot had slight edema. Her urine had trace protein, but no blood. She was started on KEFLEX capsules, 500 mg BID for 10 days. She was diagnosed with Streph A and Henoch Schonlein Purpura (HSP) nephritis. It was reported on 27-NOV-2007, a rash developed all over her left foot, edema, and left calf muscle. On 02-JAN-2008, the rash reoccurred. The patient was seen on 04-NOV-2008. Her urine was okay, but both her feet had red maculas, but no blisters. She was to see a dermatologist on 09-JAN-2008. Her rash cleared and no kidney tests were done. On 12-AUG-2008, she had a well exam and laboratory tests were performed. Her urine had 4+ blood, 3+ protein and "urine hemoglobin ++. Her urine protein was over 50, throat culture negative, and urine culture negative. On 14-AUG-2008, she saw a dermatologist. Her BUN was 9, creatinine was 0.5 and blood pressure was 102/52. Relevant laboratory diagnostics performed indicated HSP nephritis most likely post Strep, however, she also had the immunizations. On an unspecified date, she was seen by a kidney specialist. The patient recovered on an unspecified date. Upon int

Other Meds: VASOTEC

Lab Data: blood pressure, 8/14/08, 102/5; urine blood, 08/12/08, 4+ blood in urine; urine protein, 08/12/08, 3+ protein in urine; urine hemoglobin, 08/12/08, ++; urine protein (quant), 08/12/08, over 50; urine culture, 08/12/08, negative; serum blood

History: PMH: h/o HSP nephritis dx'd 11/07.

Prex Illness: Blood pressure high; Penicillin allergy; Hives

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **368035-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Nov-2009	10-Nov-2009	0	17-Nov-2009	18-Nov-2009	AZ		18-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	AHAVB342AA	1	Left leg	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	500739P		Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	0312Y	1	Right leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Vomiting

Symptom Text: Patient got a headache, nausea and vomiting.

Other Meds: None

Lab Data: None

History: Allergic to cillin family

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **368036-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Aug-2009	Unknown		17-Nov-2009	18-Nov-2009	MS	WAES0911USA01955	08-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2928AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	229X		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menorrhagia, Syncope, Vaginal haemorrhage

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter who was vaccinated at a clinic with a dose of GARDASIL during a physical for her school on 25-AUG-2009. It caused a side effect, the patient fainted at school, and had to be rushed to the hospital. She was heavily bleeding from the vagina. The daughter was not bleeding until she took the shot. The patient went back to physician and the physician said she did not know talking (crazy) referred her to another doctor. The reporter noted that other female girls did not want the shot if it messed up her daughter's body. The daughter was afraid of getting more shots because of the damages that had been done to her with this shot. She is still bleeding. The mother was trying to talk to her about going to the doctor. Additional information has been requested. 12/15/09 Medical records, VAX records received for DOS 08/11/09. Well child physical; menarche 7/08. 12/22/09 Medical records received for DOS 10/06/09. Pt. presents with vaginal bleeding since 08/24/09: dark red blood, no clots. Referred to GYN specialist. Impression: menorrhagia

Other Meds: Unknown

Lab Data: Unknown

History: Unknown 12/15/09 PMH: NKDA

Prex Illness:

Prex Vax Illns:

Vaers Id: **368050-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	28-Oct-2009	28-Oct-2009	0	17-Nov-2009	18-Nov-2009	UT		18-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU(H1N1)	SANOFI PASTEUR	UP002AA	0	Left leg	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	1	Right leg	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	500737P	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy, Loss of consciousness, Musculoskeletal stiffness

Symptom Text: Patient appeared to "pass out" after 2nd GARDASIL vaccine. Mother reports her "eyes rolled back, hands and arms were clinched and arms stiffened". Episode last 2 minutes. Pt. observed and vitals obtained for 10-15 minutes. Walked out of clinic and "passed out" again. No seizure activity 2nd time.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **368053-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Nov-2009	14-Nov-2009	0	17-Nov-2009	19-Nov-2009	CO		19-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	NULL	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Fall, Head injury, Hypotension, Loss of consciousness, Pallor

Symptom Text: PT. Jerked back and fell on the back of her head and hit the floor. She was pale, LOC for several seconds and regained and was Alert and Oriented x3. Pt's BP was low, and concern for head injury, was sent to local hospital for further evaluation.

Other Meds:

Lab Data:

History: NONE Identified

Prex Illness: NONE Identified

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **368139-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Oct-2009	21-Oct-2009	1	17-Nov-2009	19-Nov-2009	VA		19-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness transient

Symptom Text: Loss vision rt eye transeunt 30-35 sec x1.

Other Meds:

Lab Data: Sent to eye OR of eval

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **368235-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Dec-2007	14-Jan-2008	24	17-Nov-2009	18-Nov-2009	OH		01-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	1	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	42484AA		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Alopecia, Asthenia, Asthma, Asthma exercise induced, Blood pressure decreased, Chest discomfort, Condition aggravated, Confusional state, Convulsion, Dizziness, Dry eye, Ear congestion, Ear discomfort, Excoriation, Eye pruritus, Eye swelling, Fatigue, Feeling cold, Head injury, Headache, Hyporeflexia, Immune system disorder, Infectious mononucleosis, Lacrimation increased, Listless, Loss of consciousness, Malaise, Pallor, Productive cough, Sinusitis, Skin laceration, Syncope, Tongue biting, Wheezing

Symptom Text: Patient woke up feeling faint and cold. She was light headed and complained at school to several people that she felt faint. Then she did faint and she had a seizure that lasted 2 minutes. She was taken to the hospital by the paramedics. MRI, EEG all tests were normal. No explanation for this event. Next shot is June 2008. Patient appears immune-compromised. She is constantly sick and complains of fatigue. She returns to college. She is sick from Sept thru Dec. No amount of antibiotics helps. Her hair is falling out. She is pale, listless, without energy. On Dec 27, 2008, she passes out again, first thing in the morning after feeling cold and faint. Again she suffers a seizure and is unconscious for 2 minutes. She is taken to the hospital and no explanation can be found for this drop in blood pressure, syncope and seizure. Eleven months later she has another episode exactly like the first two. Throughout the year she has suffered from unexplained drops in blood pressure. She has never regained her energy level and is often sick with sinus infection like symptoms, but her sinuses are clear (x-ray) and no amount of antibiotics help. When she received the second Gardasil shot she also received the Menactra vaccine. 12/29/09 Pediatric Medical records received for DOS 01/02/08-01/05/10. PCP notified by school that pt. had first seizure activity on 01/18/08 and was transported by ambulance to hospital. DC home to f/u with neurologist, MRI and EEG. Reported instances of seizure activity on 12/30/08, 01/01/09 and 11/25/09. Referrals to allergist, cardiologist and neurologist. ```1/29/10 allergy notes rec'd from 4/2008-6/2009 with dx: Increased BA (bronchial asthma). Increased EIA (exercise induced asthma). Pt initially presented in 4/2008 with c/o increased asthma sx. C/o dry eyes, productive cough, wheezing and chest tightness with exercise. Reports Mono in 1/2008. RTO 5/29/09 with persistant cough, H/A QOD, itchy watery eyes, ear fullness and congestion since 11/08.-additional dx: sinusitis.

Other Meds:

Lab Data: No diagnosis to date. All tests are inconclusive for any problems. Clear EEGs. No heart problem. Never used any drugs. Always healthy until this. 12/29/09 Diagnostics: Normal MRI and EEG ```LABS and DIAGNOSTICS: CT Head - Abnormal.

History: none 12/29/09 PMH: Asthma; Allergic to Bactrim. ```PMH: Dry skin. Abnormal menstrual bleeding.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **368250-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-May-2007	01-Jun-2007	31	17-Nov-2009	19-Nov-2009	CO		11-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Alopecia, Anaemia, Arthralgia, Asthenia, Bedridden, Dizziness, Drooling, Facial palsy, Fatigue, Gait disturbance, Headache, Hypersomnia, Hypothyroidism, Malaise, Nausea, Neck pain, Pain, Paraesthesia, Petechiae, Somnolence, Steroid therapy, Vaccine positive rechallenge, Vomiting

Symptom Text: dizziness, nausea and malaise for several weeks after first injection (May 2007); vomiting, diffuse joint pain, weakness, sleeping constantly after second injections (July 2007); bilateral petechial rash lasting for several months, fatiguel, left sided tingling of arm and leg followed by face droop and drooling, headache lasting a few months, alopecia, and pain after her third injection (August 2007). Treated with pain medication, accupuncture, facet injections, radiofrequency rhizotomy procedures. 11/30/09 Medical records and discharge summary received for DOS 5/1-5/8 Final DX: Intractable headache and neck pain, nausea, vomiting, nausea S/P Gardasil # 1 dizzy, nausea, weakness, malaise weakness. Improved. Gardasil #2 increased vomiting, weakness, diffuse joint pain. Somnolence, fatigue. Gardasil #3 w/meningitis vaccine, constant sleeping, anemia, bil petechial rash on legs, ANA eleveated, borderline low thyroid, L side tingling, facial droop w/headache for 10 min intermittently. Alopecia. Pain clinic tx w/facet injections. 70% improved. Received additional facet injection and developed severe neck pain and headache. Nausea, vomiting. Could not get out of bed. Steroids, fluids. Much improved. D/C to home w/pain meds.

Other Meds:

Lab Data: Labs & Diags: Ct Head- no intracranial cause of headaches, Normal contrast MRA of the head, Normal CTA neck, ANA neg. ALT/SGPT 53 (H), ALBUMIN 3.4 (L), GLOBULIN 4.3 (H), MAGNESIUM, 14. (L), CA 8.1 (L), GLUC 125 (H), BUN 5 (L), SODIUM 130 (

History: PMH: depression Allergies: unk

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **368259-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	06-Oct-2009	06-Oct-2009	0	17-Nov-2009	27-Nov-2009	TX		08-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
DTAP	SANOFI PASTEUR	ACS2B037AA	1	Right arm	Unknown	
FLU	NOVARTIS VACCINES AND DIAGNOSTICS	UT3175AA	1	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0672Y	1	Left arm	Unknown	
MNQ	SANOFI PASTEUR	U3013AA	1	Left arm	Unknown	
VARCEL	MERCK & CO. INC.	0993Y	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dyspnoea, Headache, Hypoaesthesia, Nausea, Pain in extremity, Vomiting

Symptom Text: Numbness in feet, severe headaches, nausea, vomiting, stomache aches, shortness of breath 11/23/2009 PCP records for 10/6/2009, patient with c/o's leg pain. no tx noted

Other Meds:

Lab Data: xrays for headaches Labs: CBC, ESR, Ra factor, CMP, TSH and CRP all wnl

History: none PMH: chronic knee and ankle pain Allergies: NKDA

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **368367-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Nov-2009	16-Nov-2009	0	18-Nov-2009	19-Nov-2009	KY		20-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0880Y	1	Right arm	Subcutaneously	FLUN(H1N1)
TDAP	SANOFI PASTEUR	C3356AA		Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3012AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0650X	0	Left arm	Intramuscular	
FLU	SANOFI PASTEUR	U3208AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Bite, Conversion disorder, Convulsion, Epilepsy, Gaze palsy, Nausea, Staring, Tonic clonic movements, Tremor, Vomiting

Symptom Text: Possible sz activity about 2 - 2 1/2 hours after vaccines administered. H/o sz. since infant. This episode, student "stared" for about 2 mins. Emergency personnel and Dad notified. Student transported to hosp. ER via ambulance. ```3/15/10 Neurology consult received for date of service 12/14/09. Dx: epileptic seizures that may have some component of non-epileptic seizures that may be overshadowing epileptic seizures. ```11/24/09 Received ER medical records of 11/16/2009. FINAL DX: pseudoseizure Records reveal patient experienced episode of staring, shaking, then eyes rolling up & biting while at school & again in ambulance. Had similar episode on 11/14 ```02/23/10 and 03/10/10 received ED records and labs. DX: Pinworms, Abd pain, N&V. Treated with Vermox and Phenergan. ```3/10/10 ER note received for date 1/15/10. DX: seizures. CC: seen this day for c/o mulitple seizure episodes, mixture of tonic clonic and staring spells. EEG report received for date 1/7/10. EEG report WNL.

Other Meds: Valium 5mg 1/2 tab bid began 11/14/2009

Lab Data: ```02/23/10 and 03/10/10 received ED records and labs. LABS & DIAGNOSTICS: WNL

History: Seizure activity since infant ```11/24/09 Received ER medical records of 10/26/2009. FINAL DX: upper respiratory infection Records reveal patient experienced fever, sore throat, abdominal pain, vomiting & cough x 2 days, HA x 1 day. Had similar symptoms week prior as well. LABS: rapid strep neg. Allergy: codeine & PCN. ```11/24/09 Received medical records w/PMH: seizure d

Prex Illness: None

Prex Vax Illns:

Vaers Id: **368437-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Nov-2009	19-Nov-2009	--	WAES0911USA02028	19-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse practitioner concerning a patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not available). Subsequently, on an unspecified date the patient experienced seizures after the vaccination. Unspecified medical attention was sought. It was unknown if there were lab studies performed. The outcome of the patient was not reported. Upon internal review, seizures was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **368439-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		18-Nov-2009	19-Nov-2009	CA	WAES0911USA02029	19-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1130X	2	Unknown	Unknown	
	IPV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a medical assistant concerning a 15 year old female patient who on an unspecified date was vaccinated with her third dose of GARDASIL (lot # 661953/1130X) and a dose of RECOMBIVAX HB (manufacturer unknown). Concomitant vaccination included Poliovirus vaccine and Influenza virus vaccine (unspecified). After receiving GARDASIL the patient experienced seizures. Unspecified medical attention was sought. Upon internal review, seizure was determined to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **368441-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Nov-2009	04-Nov-2009	0	18-Nov-2009	19-Nov-2009	FR	WAES0911USA02121	01-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Gait disturbance, Hemiplegia, Hyporeflexia

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on 04-Nov-2009 was vaccinated IM with the first dose of GARDASIL (manufacturer, batch number and site unknown). It was reported, that the female patient was vaccinated with a second vaccine on the same day (manufacturer and type of vaccine unknown). It was reported that the patient developed 15 minutes after vaccination a hemiplegia (left side) in arm, leg and face. The patient was unable to walk. It was reported that the patient went to the physician 5 days post vaccination. The physician strongly recommended the patient to visit the neurologic ambulance. It was reported, that at this time, the palsy was recovering and the patient was able to walk again. The physician diagnosed marginal reduced reflexes, slight insecurity in walking, but no strength difference left to right side. The female patient has partly recovered. The patient's Hemiplegia (left) was considered to be an other important medical event by the reporter. Other business partner numbers include E2009-10462.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **368443-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		18-Nov-2009	19-Nov-2009	CA	WAES0911USA02210	19-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Unknown	Unknown	
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female patient who on an unspecified date was vaccinated with her second dose of GARDASIL (lot # 661953/1130X) and a dose of RECOMBIVAX HB (manufacturer unknown). After receiving the GARDASIL vaccine the patient experienced seizures. Unspecified medical attention was sought. Upon internal review, seizures were determined to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **368574-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	15-Oct-2009	16-Oct-2009	1	18-Nov-2009	20-Nov-2009	CA		20-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0968Y	0	Unknown	Intramuscular	TDAP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Myalgia, Nausea, Vomiting

Symptom Text: Pt relates adverse reactions of malaise and myalgia with GI effects of nausea and vomiting after injection #1 on 10/15/09.

Other Meds: NuvaRing

Lab Data:

History: NkA

Prex Illness:

Prex Vax Illns: 10/16/09~HPV (Gardasil)~1~22.00~Patient

Vaers Id: 368712-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Jul-2007	01-Jul-2007	0	19-Nov-2009	20-Nov-2009	--	WAES0911USA02024	20-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Throat tightness, Trismus

Symptom Text: Information has been received from a 23 year old female with penicillin, ibuprofen, and Amoxicillin allergy and a history of temporomandibular joint disorder who was vaccinated with GARDASIL in 2007 and in July 2007 after the third dose she went to the emergency room because her jaw locked. The therapy started at "the beginning of 2007". There was no concomitant medication. The consumer reported that she did not stay over night but they gave her anesthesia at the hospital and knocked her jaw back in place. The consumer reported that about four months ago she had her latex gloves on, since she works at a dentist office, and later that night her throat closed up and she went to the emergency room and was there for 6 hours and was given corticosteroids (manufacturer unspecified) and BENADRYL (manufacturer unspecified) and then she was fine. The consumer reported that another time her throat closed up again and at the hospital they gave her an epinephrine (manufacturer unspecified) pen and then she was fine. There were no labs and diagnostic tests performed. This is one of several reports received from the same source. Upon internal review the event of throat tightness treated with an EPI pen was considered to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: None

History: Temporomandibular joint disorder

Prex Illness: Penicillin allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **368733-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	08-May-2009	Unknown		19-Nov-2009	20-Nov-2009	NJ	WAES0911USA02027	20-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anaphylactic reaction, Food allergy, Inappropriate schedule of drug administration, Rash

Symptom Text: Information has been received from a pharmacist concerning her 21 year old daughter with polycystic ovarian syndrome and no known allergies who in March 2009, was vaccinated with the third dose of GARDASIL (lot number not reported). Concomitant therapy included DESOGEN. It was reported that the patient has started having severe food allergy reactions to foods that in the past she could eat with no problem after the vaccination in March of 2009. These food reactions started as rash reactions, but have become anaphylactic reactions in recent episodes. The pharmacist stated that her daughter has been in the emergency room three times in the past month. EPIPEN and oxygen were used. The patient was not admitted. At the time of the report, the patient had not recovered. The rash and anaphylactic reactions were considered to be disabling, life threatening and other medical events by the reporter. Follow-up information has been received from a registered nurse at whose office the patient received her doses of GARDASIL. On 10-SEP-2007 the patient was vaccinated with the first dose of GARDASIL (lot number unspecified) on 16-NOV-2007 the patient was vaccinated with the Second dose of GARDASIL (lot number 655154/1210U), on 08-MAY-2009 (previously reported as in March 2009) the patient was vaccinated with the third dose of GARDASIL (lot number 661953/1130X). The patient did not receive any concomitant vaccinations when GARDASIL doses was administered. The patient was taking birth control pills LOESTRIN 24. The R.N. stated that the patient had not seen in the office since 08-MAY-2009. Additional information has been requested.

Other Meds: DESOGEN; LOESTRIN 24 FE

Lab Data: Unknown

History:

Prex Illness: Polycystic ovarian syndrome

Prex Vax Illns:

Vaers Id: **368734-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Jul-2009	01-Jul-2009	0	19-Nov-2009	20-Nov-2009	FR	WAES0911USA02367	20-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Transaminases increased

Symptom Text: Information has been received from a general practitioner concerning an 18 year old female patient who had received the first dose of GARDASIL (Batch number not reported) in July 2009. 15 days after vaccination, the patient was found to have a very significant increase of transaminases, i.e. 363 for a normal range at around 54. There was no suspected viral hepatitis as all serologies were negative. The patient's transaminases rate progressively returned to normal. Everything was normal at the end of September. Upon internal review the events were considered medically significant. Other business partner numbers included: E2009-10404. Additional information has been requested.

Other Meds: Unknown

Lab Data: Serum alanine aminotransferase, ??Jul09, 363, increased

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **368735-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Sep-2009	01-Oct-2009	30	19-Nov-2009	20-Nov-2009	ID	WAES0911USA02418	20-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Pancreatitis

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with obesity and no drug reaction or allergies who in 2009 (approximately September), was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL. There was no concomitant medication. Six-eight weeks ago (approximately October 2009), the patient developed idiopathic pancreatitis one month after her second vaccination. The patient sought unspecified medical attention. The physician suggested that the patient continue with the series, but the consumer's parent decided to discontinue it. The patient had been hospitalized three times for this adverse event. At the time of the report, the patient was recovering. Additional information has been requested.

Other Meds: none

Lab Data: Unknown

History:

Prex Illness: Obesity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **368761-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Nov-2009	18-Nov-2009	0	19-Nov-2009	24-Nov-2009	TX		28-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Dyspnoea, Heart rate increased, Throat tightness, Tunnel vision

Symptom Text: Dizziness, feeling like her throat was closing, trouble breathing, tunnel vision, a roaring sound in her head, weak, fast heart rate.

Other Meds: Reglan (vaccine not specified above was dose #2 of the Gardasil vaccine)

Lab Data:

History: Asthma, allergy to Sulpha and bee stings

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **368851-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Nov-2009	18-Nov-2009	0	19-Nov-2009	20-Nov-2009	MN		17-Feb-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU	SANOFI PASTEUR	U3264DA		Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0819Y	1	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	UF499AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB312AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Did not know patient was pregnant at the time vaccines were given. ```MR received 12/6/09 for date 11/18/09. DX: wellness exam WNL. Mult. vax given. Not aware of early pregnancy. Parent and pt choose EAB, OB gave referral. No other records noted.

Other Meds:

Lab Data: + preg test

History: None

Prex Illness: Pregnant

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **369057-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	21-Oct-2009	13-Nov-2009	23	20-Nov-2009	25-Nov-2009	CA		08-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Swelling

Symptom Text: Redness, swelling 3 wks following injection. Possible local infection put on Bactrim DS, warm compresses-and told to keep f/u appt. next week.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **369058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Feb-2009	17-Feb-2009	14	20-Nov-2009	23-Nov-2009	FL	WAES0904USA01029	24-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion, Drug exposure during pregnancy, No adverse event

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy Registry product, concerning a 10 year old female with no medical history or drug allergies who on 03-FEB-2009 was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL (lot# 661530/0575X) and then discovered that she was pregnant. No adverse effects were reported. The patient sought medical attention by visiting the physician's office. There was no concomitant medication. On 16-MAR-2009 pregnancy test showed positive (LMP: 17-FEB-2009, EDD =24-NOV-2009). Follow-up information has been received from a nurse practitioner. It was reported the patient had not returned to the office for follow up. The patient had an abortion performed on 17-APR-2009. When the office contacted the patient to arrange for the second dose of GARDASIL, the patient told the nurse practitioner, "I will not be getting anymore of those shots. I have been through enough with the abortion". Follow-up information has been received from the nurse practitioner. It was reported that the patient was 20-year-old not 10-year-old as previously reported. The patient had recovered from the abortion on an unspecified date. The patient had the abortion for a number of reasons including that "she was not married and was exposed to the GARDASIL. Upon internal review, "abortion" was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, 03/16/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = 2/17/2009)

Prex Vax Illns:

Vaers Id: 369060-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Sep-2009	07-Nov-2009	50	20-Nov-2009	23-Nov-2009	IL	WAES0911USA02419	23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	2	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	9116111	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Convulsion, Depressed level of consciousness, Feeling cold, Grand mal convulsion, Grip strength decreased, Headache, Musculoskeletal stiffness, Postictal state, Posturing, Tonic clonic movements, Unresponsive to stimuli, Urinary incontinence

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with no drug reactions/allergies and a history of learning disability and cognitive impairment who on 23-JAN-2009 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot # 660557/0072X). There was no concomitant medication. On 20-MAR-2009 the patient received the second dose of GARDASIL (lot # 660557/0072X) and on 18-SEP-2009 the patient received the third dose of GARDASIL (lot # 663452/0671Y). On 07-NOV-2009 the patient developed a seizure and was hospitalized for 2 to 3 days. The physician saw the patient on 13-NOV-2009 "today" and the patient's mother said the patient was "fine". The patient was on an unspecified antiseizure medication. A neurology consult was pending. MRI results were pending, cat scan and blood tests were normal. Seizure was considered to be immediately life-threatening and disabling. Additional information has been requested. 11/23/2009 Out-patient progress notes and laboratory test reports received for DOS 09/18/2009-11/13/2009. Assessment: Seizure Disorder Patient had generalized seizure (2 episodes). Hospitalized 11/07/2009 through 11/09/2009. Progress note of 11/13/2009 notes patient alert and oriented X3 and neuro intact. 12//8/09 Inpatient hospital records received. Service dates 11/7/09 to 11/9/09. Assessment: Generalized Tonic/Clonic Seizure. Mother heard strange noise, found patient stiff, head turned to left. Tonic/Clonic movements of limbs followed by postictal state. Urinary incontinence. Presents unresponsive. Seizure in ER. Cold sensation. Headache. Hand grasp weak. Slow to answer questions.

Other Meds: none

Lab Data: Magnetic resonance, results pending; computed axial, normal; diagnostic laboratory, normal 11/23/2009: LABS and DIAGNOSTICS: Cat scan WNL, BMP WNL, CBC WNL, urine pregnancy test negative and urine drug screen negative. 12//8/09 Inpatient

History: FMH: Patient has first cousin with epilepsy./rem 12//8/09 Inpatient hospital records received. Service dates 11/7/09 to 11/9/09. Sickle Cell Trait (+). "Shakes a lot". Head trauma in 2002 and 2003. Learning difficulty. Behavioral problems. Stutters.

Prex Illness: Learning disability; Cognitive impairment

Prex Vax Illns:

Vaers Id: **369063-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Aug-2009	01-Aug-2009	0	20-Nov-2009	23-Nov-2009	FR	WAES0911USA02488	25-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Embolism venous, Visual impairment

Symptom Text: Information has been received from a physician concerning a >40 year old female, who in August 2009, was vaccinated IM with 0.5 ml first dose of GARDASIL (dose and lot number not reported). This report was part of a study. Two months after the vaccination (approximately in October 2009), the patient had a visual problem that after consulting with her ophthalmologist, the patient was diagnosed with eye thromboemboli. The patient went to the physician for medical care and the visual problem was only recovered by 10%. In October 2009, the patient went again to the physician for medical care but seeing a different doctor and the patient was diagnosed with venous thromboemboli. At the time of the report the outcome of the patient was not recovered. At this time, relationship of eye thromboemboli vena to study therapy is unknown. The physician felt that the Thrombo emboli vena was considered to be disabling. Additional information has been expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **369112-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Jul-2008	02-May-2009	296	20-Nov-2009	25-Nov-2009	PA		10-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0274X	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Conversion disorder, Convulsion, Dysarthria, Intensive care, Tremor

Symptom Text: Onset seizures suddenly 5/2/09 while skating, treated 5 hrs at ER then transferred to Ped ICU x 4 days episodes. Had 2 more seizure episodes 5/18/09, 6/2/09. ER visits, DILANTIN used and d/c 6/6/09. 11/23/2009 HR and DC summary for 5/2-5/6/2009. Patient with seizure-like activity with rt sided tremors and slurred speech. Tx: IV Ativan and Dilantin, ABX and Acyclovir. Psych consult impression was conversion disorder

Other Meds: ADVAIR 250 AM, PM; MAXAIR 1 puff

Lab Data: All tests negative (MRI; CT; Blood; Spinal Tap; EEG; Video EEG) Labs: CBC, CMP, urine tox screen, EB virus, Enterovirus, CSF cell ct and culture, HSV PCR panel, all negative/normal Dx studies: CT Head wnl, EEG wnl, VEEG wnl, MRI brain no

History: Asthma since 4 y.o. - mild; Medication PRN; No other PMH: Asthma as a child now resolved Allergies: NKDA

Prex Illness: none

Prex Vax Illns:

Vaers Id: **369126-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Nov-2009	12-Nov-2009	0	20-Nov-2009	25-Nov-2009	CA		30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	0267Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Presyncope, Tonic clonic movements, Vomiting

Symptom Text: Brief (5-10 seconds) tonic - clonic movements of the arm followed by vaso-vagal reaction including drop in blood pressure to 73/43 and HR 53 with steady increase to normal. Pt also had emesis. She left clinic when stable, but then about 2 hrs later her mother returned for copies of note prior to taking pt to ER with repeated emesis and dizziness.

Other Meds: NAPROSYN

Lab Data: BP 73/43; HR 53

History: Possible UTI; constipation

Prex Illness: Back pain; possible UTI

Prex Vax Illns:

Vaers Id: **369179-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Mar-2008	01-Jun-2009	457	20-Nov-2009	23-Nov-2009	--	MA20093641	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Apgar score normal, Caesarean section, Drug exposure during pregnancy, Foetal disorder, Streptococcal identification test positive

Symptom Text: Initial case report received from a physician and registered nurse via Vaccine Adverse Event Reporting System (VAERS) on 06 NOV 2009. A 17-year-old female patient was vaccinated with FLUVIRIN (batch no. unknown) and GARDASIL (first vaccination) on 1 MAR 2008. The patient became pregnant, last menstrual period (LMP) was on 10 SEP 2008. The delivery date was estimated for 08 JUN 2009 by early ultrasound. A caesarean section due to non-reassuring fetal heart rate was performed on 01 JUN 2009. The patient was tested positive for group B streptococcus and was treated with intravenous antibiotics during labor. The baby's apgar scores were 7 at one minute, 8 at five minutes and 9 at ten minutes. The patient had recovered at the time of the report.

Other Meds: PRENATAL

Lab Data:

History:

Prex Illness: UNKNOWN

Prex Vax Illns:

Vaers Id: **369193-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Nov-2009	20-Nov-2009	0	20-Nov-2009	23-Nov-2009	CO		23-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	500721P		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0249Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incontinence, Nervousness, Pallor, Syncope

Symptom Text: Following the administration of seasonal flumist, Gardasil, and PPD Mantoux test, patient became faint, pale, shaky, and incontinent. She did not lose consciousness or fall. Patient assisted to lie down with feet elevated, drink two juice boxes, cool rags placed on forehead and neck. Within 2 minutes, patient returned to normal color, and no longer was faint or dizzy. Paitient instructed to sit in chair and remain seated for 15 minutes prior to leaving clinic. Upon leaving clinic, patient continued to be free of dizziness or faintness, and kept normal coloring.

Other Meds: PPD Mantoux Test Sanofi Pasteur Lot # C3150AA Left Forearm. Any other medications or adverse events previously are unknown.

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **369237-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Oct-2008	01-Oct-2008	0	21-Nov-2009	29-Nov-2009	HI		30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Tinnitus

Symptom Text: minutes after vaccination tinnitus and syncope

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **369279-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Dec-2008	21-Dec-2008	0	22-Nov-2009	29-Nov-2009	FR		30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Loss of consciousness, Muscular weakness, Nausea, Rash

Symptom Text: My daughter blacked out immediately after the vaccination, nausea, weakness in her limbs, continued headaches, severe rash on her face

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **369358-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Nov-2009	23-Nov-2009	0	23-Nov-2009	27-Nov-2009	VA		30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0455Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Hyperhidrosis, Hypotension, Syncope

Symptom Text: Pt became faint, sweaty, and "I cannot see". Immediately seated pt with head down - water and crax and peanut butter given as she felt better. BP 78/50. P60. Had pt recline. BP 80/50. P-52. Pt had very little breakfast.

Other Meds:

Lab Data:

History:

Prex Illness: None per pt

Prex Vax Illns:

Vaers Id: **369360-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Jun-2009	26-Jun-2009	17	23-Nov-2009	24-Nov-2009	--	WAES0907USA00954	25-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1546X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Asthenia, Back pain, Blood product transfusion, Demyelination, Dysphagia, Dyspnoea, Dysstasia, Eating disorder, Endotracheal intubation, Feeling abnormal, Gastrointestinal tube insertion, Guillain-Barre syndrome, Heart rate increased, Hypoaesthesia, Intensive care, Mobility decreased, Muscular weakness, Pain, Pain in extremity, Paraesthesia, Paralysis flaccid, Plasmapheresis, Pneumonia, Posture abnormal, Pyrexia, Respiratory failure

Symptom Text: Information has been received from a physician's assistant who received an e-mail from a family friend, concerning a 12 year old female patient who a "couple of weeks before" in approximately June 2009, was vaccinated with a dose of GARDASIL vaccine. On approximately 30-JUN-2009, the patient was diagnosed with Guillain Barre syndrome. The patient was admitted to the hospital the night of 30-JUN-2009. As of 01-JUL-2009, the Guillain Barre syndrome continued to move throughout the patient's body, affecting her lungs. The patient's parents consented to induce her into a coma. Per the patient's father, his daughter has been moved to a more restrictive area of the Pediatric Intensive Care Unit and was intubated in the morning of 02-JUL-2009. It was reported that with the "machine assisting the patient in breathing", she is getting more oxygen and resting more comfortably which is a "good thing", since before of the intubation she was expending all of her energy just trying to breath, and she could not get in a comfortable position with the constant pain. In the patient's current semi comatose state, she has opened her eyes and has moved her limbs a little bit. It was reported that the patient has run a fever so she has been started with antibiotics. The patient's father stated that the longer his daughter is assisted in breathing, the greater the chances are that she will need a tracheotomy and she might be hospitalized for an additional month. The reporting physician's assistant's friend stated that there is a good chance that the patient's Guillain Barre syndrome was an adverse reaction to the immunization with GARDASIL vaccine. At the time of reporting the patient had not recovered. The health care professional contacted during telephone follow-up could not supply the following information: date of birth, exact date (s) of vaccination, dose number, lot number, healthcare provider name and contact information. Guillain Barre syndrome and fever considered to be disabling, life threatening and required intervention to

Other Meds: LAMICTAL

Lab Data: Spinal tap, 06/??/09; Chest X-ray, 06/??/09; Electromyography, 06/??/09, demyelinating process consistent with Guillain-Barre/axonal damage; Magnetic resonance, 06/??/09, demyelinating process consistent with Guillain-Barre/axonal damage

History: Absence seizure; sore throat; fever; convulsion

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **369368-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		23-Nov-2009	24-Nov-2009	--	WAES0911USA02417	25-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Paralysis

Symptom Text: Information has been received from a medical assistant who heard from a physician's assistant concerning some patients who were vaccinated with unspecified dose of GARDASIL (lot#, route and site of administration not reported). Subsequently, the patients became blind and paralyzed. At the time of this report, the patient's outcomes were unknown. Upon internal review, blind and paralyzed were considered to be other important medical events. Attempts are being made to verify the existence of an identifiable patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **369370-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Nov-2009	05-Nov-2009	0	23-Nov-2009	24-Nov-2009	FR	WAES0911USA02557	25-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Gaze palsy, Loss of consciousness, Malaise, Presyncope

Symptom Text: Information has been received from a general practitioner concerning a 14.5 year old female with a history of vagal malaises and described as a neurotonic patient, who on 05-NOV-2009 was vaccinated with the first dose of GARDASIL (route and LOT# not reported). Three minutes after vaccination, the patient experienced a loss of consciousness associated with convulsive and ocular revulsion. Vagal malaise (or impressive malaises) or convulsive seizure were two evoked diagnoses. Constants were correct. The loss of consciousness lasted for 10 seconds. There was no sequelae, no pain at the moment of the injection. The patient consulted to the Emergency Unit Care where the diagnosis of vagal malaise was established without exam. A neurological consultation was planned to assess whether it was a convulsion or not. To be noted that when the patient described the events to her mother, the latter experienced a vagal malaise. At the time of reporting, the patient had recovered. The AEs were considered to be serious as other medical important events. Other business partner numbers included: E2009-10520. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Vasovagal symptoms

Prex Illness:

Prex Vax Illns:

Vaers Id: **369371-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		23-Nov-2009	24-Nov-2009	FR	WAES0911USA02601	25-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a general practitioner, for the Pregnancy Registry for GARDASIL, concerning a 15 year old female patient with no relevant medical history and no treatment who received the first dose of GARDASIL (Batch No. not reported) on an unspecified date while she was 3 month pregnant. She consulted with the reporter to receive the second dose of GARDASIL as she was in her 5th month of pregnancy but she still did not know that she was pregnant. She went abroad to have an induced abortion practiced as she was beyond her 5th month of pregnancy. There was no medical cause which justified the induced abortion. No reaction was reported after the first dose of GARDASIL. It was noted that the case was not enrolled in the GARDASIL registry (patient's initials and date of birth are unknown). Induced abortion was considered to be an other important medical event. Other business partner numbers include: E2009-10515. No further information is available.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **369372-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Nov-2009	11-Nov-2009	1	23-Nov-2009	24-Nov-2009	FR	WAES0911USA02603	25-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	LH42160	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Epilepsy

Symptom Text: Information has been received from a healthcare professional concerning a 15 year old female patient who received the first dose of GARDASIL (batch number LH42160) on 10-NOV-2009 in the evening and 10 hours later, in the morning of 11-NOV-2009, she experienced a seizure of rolandic epilepsy. The reaction was described as moderate. The patient recovered within an unspecified period of time. The patient had experienced three seizures of rolandic epilepsy three years before. She had not experienced other isolated seizures until then. She was taking no treatment: No adverse reaction had occurred following childhood vaccinations. It is noteworthy that she had come back from holiday with a jet lag and therefore she was tired, and she had worked late on computer. These risk factors were reported to be the usual triggering factors for that kind of seizures. Seizure of rolandic epilepsy was considered to be an other important medical event. Other business partner numbers include E2009-10519.

Other Meds: Unknown

Lab Data: Unknown

History: Epileptic seizure

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **369388-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Nov-2009	04-Nov-2009	0	23-Nov-2009	24-Nov-2009	FR	WAES0911USA02907	25-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ29430		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from health authority (case# 106293) (local case# IT503-09) concerning a 14 year old female who at 8 AM on 04-NOV-2009 was vaccinated with GARDASIL (lot# NJ29430, batch# NK19200) (route and site of administration not reported). At 5 PM on 04-NOV-2009, she presented with afebrile convulsion that lasted few minutes and led to hospitalization. Final outcome was not reported. There was no previous medical history reported. Other business partner numbers included: E2009-10636. No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **369480-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	15-Oct-2009	15-Oct-2009	0	23-Nov-2009	27-Nov-2009	PA		30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dizziness, Pyrexia

Symptom Text: Vaccine given @ 0945 ; began feeling dizzy and developed chills around 1700 ; Temp of 101 degrees - relieved by TYLENOL. Symptoms persisted until 0300 10-16-09. Fever controlled after TYLENOL.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None Known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **369649-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	27-Feb-2009	06-Mar-2009	7	24-Nov-2009	29-Nov-2009	CA		09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Arthritis, Eosinophil count, Eosinophilia, Fatigue, Haematuria, Hypoaesthesia, Joint stiffness, Joint swelling, Leukocytosis, Myalgia, Neutropenia, Oropharyngeal pain, Paraesthesia, Pyrexia, Red blood cell sedimentation rate decreased, Red blood cell sedimentation rate increased, Testicular swelling, Thrombocytosis

Symptom Text: sore throat, high fever followed by total body joint pain and swelling. treatment began with a prednisone shot 11/25/09 ED Notes for DOS 01/17/09. Final DX: Inflammatory arthritis, systemic symptoms of fever and fatigue, sore throat self-limiting, leukocytosis infcluding eosonophilia/neutrophilia, and microscopic hematuria. Pt presented to ED with 2 wk hx of joint pain, swelling and stiffness. The pain started in her hands and generalized to her jaw. Pt did not have fever, but had sore throat for 3 days, which went untreated. Pt noted that she was unable to form a fist. On 01/14/09, Pt was seen in urgent care and tests confirmed leukocytosis, elevated ESR, and hematuria. NSAIDs, Vicodin and prednisone did not resolve the arthralgias. Upon physical assessment, Pt was found to have a recent numbness, tingling of hands that resolved. Pt's physician suspected a diagnosis of possible adult onset of Still disease based on her symptoms, although the Pt did not meet all the criteria. Prednisone 20 mg/day was started. Pt scheduled for a follow up visit in 1 month. 11/25/09 Follow up visit notes for DOS 04/29/09. DX: Inflammatory arthritis, leukocytosis, thrombocytosis, recent microscopic hematuria. Pt complained of ongoing difficulties with wide spread joint pain and fatigue. Pt did not have visible swollen joints and prednisone was thought to have resolved this event. Physician reduced prednisone dose to 15 mg/day. Follow up visit was scheduled for 2 months. 11/25/09 Follow up visit notes for DOS 06/26/09. DX: Inflammatory arthritis and microscopic hematuria, indeterminant significance. Pt complained of uncontrolled pain and swollen joints of hands with morning stiffness that improves as the time goes on. Follow up visit scheduled for 2 months. 11/25/09 Follow up visit notes for DOS 07/02/09 DX: Hematuria. Pt felt better with no pain or swelling and wanted to be off prednisone. Follow up visit scheduled for 2 months. 11/25/09 Follow up visit notes for DOS 09/04/09 DX: Inflammatory polyarthritis

Other Meds:

Lab Data: diagnosed with stills disease an auto immune disease similar to rheumatoid arthritis 11/25/09 Laboratory tests showed WBC 17.9 with elevated neutrophils, eosonophils, monocyte count, hemoglobin 12.5, platelets 306 and ESR 48. 11/25/

History: 11/25/09 Allergies: Erythromycin allergy or intolerance.

Prex Illness: 11/25/09 PMH: Tonsillectomy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **369735-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Nov-2009	16-Nov-2009	0	24-Nov-2009	24-Nov-2009	AL		24-Nov-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1312X	0	Left arm	Unknown	
VARCEL	MERCK & CO. INC.	1070Y	1	Left arm	Unknown	
FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500761P	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: Maya began to feel very dizzy and had a headache starting about 12hrs after the vaccines were given. There was no fever, stiff neck, or nausea. She was referred to the ER for evaluation but left without being seen due to long wait. Evaluation in my office the next day - everything ok.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **369816-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Nov-2009	11-Nov-2009	1	24-Nov-2009	27-Nov-2009	CA		30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	43060AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0702X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Nausea, Pain, Pyrexia

Symptom Text: 11-11-09 - fever, body aches, nausea, fever reported at 100.9 oral. 11-12-09 - fever gone, left upper arm swollen.

Other Meds: Tetriacyclene; Claritan

Lab Data:

History: Allergy; iodine, tyterol; vinegar, hair dye

Prex Illness: None

Prex Vax Illns:

Vaers Id: **369894-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Nov-2009	11-Nov-2009	0	24-Nov-2009	27-Nov-2009	CA		12-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Foaming at mouth, Gaze palsy, Loss of consciousness, Presyncope, Tonic clonic movements, Vomiting

Symptom Text: Within a minute of receiving HPV vaccine pt began to have a seizure. Tonic clonic movements with eyes rolling, foaming at the mouth with vomiting. 12/2/2009 PCP records for 11/16 and 11/25/2009, patient with c/o's lightheadedness, vomiting, LOC for 10 seconds post vaccine. Dx vasovagal syndrome. No tx noted

Other Meds: None

Lab Data: Labs/Dx studies: None

History: None known PMH: None Allergies: NKDA

Prex Illness: None known

Prex Vax Illns:

Vaers Id: **369904-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Apr-2009	19-Apr-2009	12	24-Nov-2009	25-Nov-2009	FR	WAES0911USA02721	30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NM55660	1	Unknown	Intramuscular	
	HEP	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Cell death, Henoch-Schonlein purpura, Leukocytoclastic vasculitis, Necrosis, Petechiae, Purpura, Skin lesion

Symptom Text: Case received from the health authorities (reference number 2009-03529) on 10-NOV-2009, and transmitted by SPMSD. A 13 year old female patient had received the first dose of GARDASIL (Batch # NM55660) via intramuscular route on 06-FEB-2009, and the second dose of GARDASIL (Batch # NS35180) via intramuscular route on 07-APR-2009, date on which she also received a dose of RECOMBIVAX HB (Batch # not reported) via intramuscular route. On 19-APR-2009, she developed patechiae and purpura on both lower limbs. The events resolved spontaneously. On 24-APR-2009 and 25-APR-2009, the patient experienced mild abdominal pain without nausea, vomiting or diarrhea. She "denied sore throat". On 27-APR-2009, there was a major recurrence on lower limbs, asymptomatic. The patient was admitted to the hospital from 30-APR-2009 to 03-MAY-2009 on dermatology ward. The patient's general health was reported as good, blood pressure was normal, heart rate was normal, there was no fever, heart beating was normal too. Cardio respiratory auscultation was normal. The abdomen did not show any abnormalities. There was no lymph node enlargement, and no abnormalities on the oral cavity. On a dermatological level, pupuric lesions were palpable on the lower limbs below the knee. The diagnosis was leukocytoclastic vasculitis in henoch-scholein purpura, probably postvaccinal. The diagnosis was confirmed by histological examination on 30-APR-2009. There were a few areas of basal keratinocytic necrosis, in the superficial and middle dermis, substantial extravasation of erythrocytes and some perivascular and partly interstitial neurophilic infiltrate, with karyorrhexis. Signs of fibrinoid necrosis were present on the wall of a few small blood vessels. There was no thrombosis, but some eosinophils in the infiltrate, which confirmed leokocytoclastic vasculitis. Antinuclear, anti-DNA and anti-neutrophil cytoplasmic antibodies (ANCA) tests were negative. Direct inmmunofluorescence was negative. Throat swab and antistreptolysin antibody test were both normal. A

Other Meds: Unknown

Lab Data: Diagnostic pathological examination, 30Apr09, diagnosis of leukocytoclastic vasculitis in henoch-schonlein purpura; Blood pressure measurement, normal; Allergen skin test, performed for RECOMBIVAX and GARDASIL was negative; Dermatological e

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **369907-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Nov-2009	11-Nov-2009	0	24-Nov-2009	27-Nov-2009	PA		30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2872AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None stated

Other Meds: EFFEXOR; TRAZADONE; Lorantidine; PREVACID; BENADRYL

Lab Data: None

History: Anxiety disorder; GERD

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **369908-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Nov-2009	25-Nov-2009	FR	WAES0911USA02806	30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Idiopathic thrombocytopenic purpura

Symptom Text: Information has been received from a published article concerning a teenage girl (age not stated) who on an unspecified date was vaccinated with the third dose of GARDASIL vaccine, Ten days after vaccination the patient experienced idiopathic thrombocytopenic purpura and was hospitalized. At last follow-up, she was being monitoring as an outpatient and her platelet count was improving. This is one of several reports received from the same source. Additional information has been requested. A copy of the published article is attached as further documentation on the patient's experience.

Other Meds: Unknown

Lab Data: Platelet count, improving

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **369911-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Jan-2008	29-Jan-2008	0	24-Nov-2009	25-Nov-2009	FR	WAES0911USA02908	30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0510U	2	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dermatitis atopic, Diarrhoea, Nausea, No reaction on previous exposure to drug

Symptom Text: Case received from a health care professional on 14-NOV-2009. This case is poorly documented. It was forwarded too late by a pharmacist. It was reported by a gynecologist that a 16 year old female patient with history of neurodermatitis who was vaccinated with the first and the second dose of GARDASIL on 14-JUL-2007 and 25-SEP-2007 and were all well tolerated. On 29-JAN-2008 the patient was vaccinated with a third dose of GARDASIL (batch # NG20180, lot # 0510U, injection route not reported) into the left upper arm. Unspecified time p.v. the patient developed diarrhoea, persistent nausea and as written atopic dermatitis (not otherwise specified). At the time of completing the reporting form (Date 26-APR-2008) she was hospitalized and had not recovered. Other business partner numbers include: E2009-10554. No further information available.

Other Meds: Unknown

Lab Data: Unknown

History: Neurodermatitis

Prex Illness:

Prex Vax Illns:

Vaers Id: **369915-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Nov-2009	25-Nov-2009	FR	WAES0911USA02975	30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Diplegia, Dizziness, Fatigue, Monoplegia, Muscle spasms, Myalgia, Pain in extremity, Vaccine positive rechallenge

Symptom Text: Information has been received from a published article, concerning a female patient (age not stated) who on an unspecified date was vaccinated with the first dose of GARDASIL. One week later developed dizziness, muscle pain, joint pain, weakness and cramps. Before administration of the second dose, she had experienced both recovery and recurrence of her symptoms. A neurological examination showed marked fatigue and near paralysis of her legs and arms. Her symptoms recurred 2 to 3 weeks after her third dose of vaccine. She recovered within a few days but, approximately 6 weeks after her third dose, she experienced a fourth attack marked with only dizziness and pain in hands during physical activity. At the time of reporting the patient's outcome was no stated. Upon internal review paralysis was considered to be an other important medical event. This is one of several reports received from the same source. Additional information has been requested. A copy of the published article is attached as further documentation of the patient's experience.

Other Meds: Unknown

Lab Data: Neurological examination, see narrative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 369943-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	03-Nov-2009	05-Nov-2009	2	24-Nov-2009	25-Nov-2009	PA		18-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	500741P	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Arthralgia, Balance disorder, Diarrhoea, Eye disorder, Eye pruritus, Eyelid margin crusting, Fall, Gait disturbance, Headache, Joint stiffness, Muscular weakness, Pain in extremity, Paraesthesia, Rash, Tendonitis, Viral infection, Vision blurred, Weight bearing difficulty

Symptom Text: Pain in the legs and inability to bear weight. Started on 11/5/09 (about 8 pm) and was seen in the medical office on 11/6/09 and then in the ER, (hospital) the same night; and again on 11/9/09. Transferred to another hospital; discharged on 11/11/09. Was still not ambulating. LP done - was normal. 12/2-12/8 Discharge summary and medical records received for DOS 11/9-11/11. Final DX: Lower extremity pain. PTSD. Acute onset tingling bil feet. Progressive sharp pain ascending to knees. Fell to floor. Legs too weak to walk. Transient macular rash on face resolved. Knee/ankle joint pain. Diarrhea. Psych eval revealed PTSD and h/o abuse. All diags WNL. Improved w/NSAIDs. OT/PT planned. ``` PCP medical records, PT, and rheumatology consultations received. Service dates 11/6/09 to 12/12/09. Assessment: Acute onset enthesitis with overlapping neuropathic pain features. R/O Guillain-Barre Syndrome. Patient presents with bilateral leg pain, unable to walk. Fell in in house previous night. Tingling in feet, recent viral illness. Headache, blurred vision - to have eyes checked by optometrist. Rash on face and arm. Left eye shut, crusty, itching. Joint stiffness, muscle weakness, ankle pain, foot pain, hip pain, knee pain. Balance problems.

Other Meds:

Lab Data: LP - normal Labs & Diags: creat 0.32 (L), K 3.5 (L), Leg X-ray WNL

History: None Allergies: NKA ``` Sexual abuse. Apnea at birth. Wrist and ankle sprain injuries.

Prex Illness: Rash on face-around mouth and chin; vesicles in mouth; Dx: Viral Syndrome

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370032-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Nov-2009	23-Nov-2009	0	24-Nov-2009	27-Nov-2009	MN		30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope, Syncope

Symptom Text: Vasovagal reaction, patient fainted

Other Meds:

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **370035-1** **Related reports:** 370035-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	31-Jul-2008	31-Aug-2008	31	24-Nov-2009	30-Nov-2009	KS		22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Clonus, Condition aggravated, Fatigue, Fibromyalgia, Headache, Loss of proprioception, Musculoskeletal pain, Pain in extremity, Pharyngitis streptococcal, Photophobia, Sleep disorder, Tremor, Vaccine positive rechallenge, Weight decreased

Symptom Text: First administration of Gardasil in 07/08 with bilateral hand tremor beginning 08/08. Second administration on 12/31/08 with hand pain beginning 02/09 and extending to wrists, elbows, shoulders, back, hips, knees, ankles, feet and toes by 04/09. Final administration is 07/09 with immediate increase in pain. The physician was asked about possible reaction after the first dose. The physician advised there was no connection. Patient has been dx with fibromyalgia; however, no successful tx at this time. Along with the tremor, other neurological involvement is indicated by bilateral clonus and proprioceptive symptoms in her legs. Patient also suffers headache and significant fatigue. Patient has been unable to sleep in bed for several months and does not get solid, consecutive hours of sleep. She has lost 20 pounds since this past Spring. There are days patient requires moderate assistance for sit-to-stand. 12/04/09 Consult note for DOS 01/30/09. DX: Essential tremor Pt c/o hand tremor that is bothering when writing for 4-5 mos. On neurological exam: weight, head and height were all above 90th percentile; mild postural tremor BUE. Physician considered this diagnosis of essential tremor as benign and suggested reducing caffeine and stress. Pt to follow up prn. 12/08/09 Follow up consult for DOS 11/09/09. DX: Fibromyalgia Pt c/o L knee pain, neck pain, inguinal pain, finger joint pain, hand pain, wrist joint pain, elbow joint pain, shoulder joint pain, back pain in Lumbar spine, buttock pain, and hip. Musculoskeletal exam: confirmed joint pain in L fingers, shoulder, L and R knees, L and R ankles; tx: Soma. Pt c/o pain continuing.

Other Meds:

Lab Data: I do not have specific results. They have completed blood work and x-rays that ruled out rheumatoid arthritis. Patient has also had an MRI of her pelvis. I was advised that all testing has been negative, but am not sure for which conditions

History: allergic to penicillin and seasonal allergies 12/08/09 Follow up consult for DOS 11/09/09. PMH: Hypothyroidism; Allergies: Amoxicillin, Zithromax, Augmentin.

Prex Illness: No

Prex Vax Illns:

Vaers Id: **370035-2 (S)** **Related reports:** 370035-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Sep-2008	28-Oct-2008	29	16-Dec-2009	17-Dec-2009	--	WAES0912USA00997	17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Cough, Dizziness, Fibromyalgia, Insomnia, Oropharyngeal pain, Pain, Sinus disorder, Tremor

Symptom Text: Information has been received from a physician concerning a female with rhinitis allergic and allergic reaction to antibiotics who on 29-SEP-2008 was vaccinated with the first dose of GARDASIL (lot# not reported) and on unspecified dates vaccinated with the second and third dose of GARDASIL (lot# not reported). Concomitant therapy included ALLEGRA and NASONEX. It was unspecified if any other vaccines were administered. After the first dose of GARDASIL, unknown how long post vaccination, the patient experienced pain at multiple sites, dizziness, and insomnia. Unspecified medical attention was sought. The patient was diagnosed by rheumatologist with fibromyalgia. It was also reported that the patient will also have follow up consult with a neurologist. Follow up information has been received from a registered nurse and a licensed practical nurse concerning the 13 year old female patient. The registered nurse reported that the female patient was with a concurrent condition of allergic rhinitis. The patient on 29-SEP-2008, 31-DEC-2008 and 23-JUL-2009 was vaccinated with her first, second and third dose of GARDASIL respectively. The patient was first seen in their office on 02-DEC-2009. The patient was scheduled to see a pediatric neurologist. The licensed practical nurse provided additional information. She confirmed that the patient was on concomitant medications ALLEGRA and NASONEX for the concurrent condition of allergic rhinitis. The patient's antibiotic allergies were to amoxicillin, AUGMENTIN and ZITHROMAX. The patient was vaccinated on 29-SEP-2008, 31-DEC-2008 and 23-JUL-2009 with her first, second and third dose of GARDASIL (lot numbers were 660618/0572X, 660618/0572X and 661952/1129X) respectively. The nurse reported the patient was seen on 02-DEC-2008 with "hand shaking" that started five weeks prior. At the January 2009 office visit, the problem persisted. Other office visits were on 13-APR-2009 for a sinus problem, 02-SEP-2009 for a sore throat, and 18-SEP-2009 for a cough. The patient was last seen in th

Other Meds: ALLEGRA; NASONEX

Lab Data: Unknown

History:

Prex Illness: Rhinitis allergic; Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370051-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Jul-2009	05-Aug-2009	6	24-Nov-2009	27-Nov-2009	OH		21-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2926AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0087Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness unilateral, Ophthalmological examination abnormal, Optic neuritis, Optic neuropathy, Visual field defect

Symptom Text: 7/30/09 - 1st Gardasil shot. 8/5/09 - R eye losing vision, painless, 8/14/09 - eye exam - both abnormal eyes, visual fields. 10/12/09 - 2nd Gardasil shot. 10/23/09 - eye exam #2 - both VF abnormal R > L. ``` MR received 12/7/09 and 1/15/10 for dates 7/30/09 and 11/24/09. DX 7/30/09 wellness exam vaccines given. DX 11/24/09 Eye exam consultation: post vaccination bilateral optic neuropathy, inflammation at bilat optic nerve. CC: right side vision changes x1wk after gardasil vax, visual impairment worsening from time of vax to current exam date.

Other Meds: None

Lab Data: / Pictures taken 1. Abnormal pupil R > L 2. Abnormal VF R > L 3. Abnormal OCT R > L

History: None

Prex Illness: None #1; Hoarseness with #2

Prex Vax Illns:

Vaers Id: **370139-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Jan-2009	01-Feb-2009	12	25-Nov-2009	30-Nov-2009	MA	WAES0908USA03467	03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	1	Left arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anxiety, Arthralgia, Arthritis, Arthritis allergic, Arthritis reactive, Costochondritis, Erythema, Fatigue, Hyperhidrosis, Leukocytoclastic vasculitis, Malaise, Musculoskeletal stiffness, Myalgia, Oedema peripheral, Pain, Pruritus, Pyrexia, Rash, Rash macular, Red blood cell sedimentation rate increased, Skin test, Urticaria, Urticaria cholinergic, Weight increased

Symptom Text: Information has been received from a physician concerning a female "sophomore in high school" student patient who on an unspecified date was vaccinated with the first 0.5 mL GARDASIL and on unknown date received the second dose of GARDASIL. It was reported that the patient developed rash after getting two doses of GARDASIL. The patient sought unspecified medical attention. At the time of reporting the patient had not recovered. Follow up information has been received from a physician via medical records, concerning a 16 year old female student with allergy to DILAUDID, and a medical history of adenoidectomy, endotracheal intubation insertion, tonsillectomy, PE tubes and an orthopedic surgery (internal fixation of left arm fracture), who on 03-NOV-2008, was vaccinated with the first dose of GARDASIL (Lot No: 657737/0522U), in the left arm. On 20-JAN-2009. the patient was vaccinated with the second dose of GARDASIL (Lot No: 659437/1266U), in the left arm. Concomitant medications included doxycycline, TYLENOL and ZYRTEC. In February 2009, the patient experienced costochondritis. On 02-APR-2009, the patient presented for evaluation of one month of sickness with hives and then migrating joint pain. The patient presented with complaints of pain to all the joints and muscle pain. On of a scale of 10 the pain was 7. The severity of her fatigue on a scale of 10 was 7. The patient experienced morning stiffness duration 10 minutes. The physician reported that the patient stated that this condition started suddenly. The symptoms had been intermittently present for the last one month, with waves of hives and overall aching and now with recurrent erythema but without itching. The patient noted fevers as coming off the MEDROL and had sweats when on the steroids. The physical exam did not show any abnormality, except for the musculoskeletal exam that showed joints affected primarily in the ankle, and possible inflammation of the MTP. The skin exam showed scattered macules of the arms and more confluent itchy area of the skin on

Other Meds: TYLENOL; ZYRTEC; doxycycline

Lab Data: Serum creatine kinase, 05/06/09, Normal; Urinalysis, 04/02/09, Protein in urine; Erythrocyte, 05/06/09, elevated: 49

History: Surgery; Arm fracture; Orthopedic procedure; Endotracheal intubation; Tympanostomy tube insertion; Tonsillectomy; Adenoidectomy

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 370141-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Nov-2009	03-Nov-2009	0	25-Nov-2009	30-Nov-2009	FR	WAES0911USA02903	30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Confusional state, Cyanosis, Headache, Hemiplegia, Hypersomnia, Loss of consciousness, No reaction on previous exposure to drug, Pallor, Presyncope, Syncope

Symptom Text: Initial case was reported on 17-Nov-2009 by health Authority (HA ref. DK-DKMA-20093679). It was reported that a 12 year old female patient was vaccinated with the second dose of GARDASIL (yeast) (intramuscularly, batch and site of administration not reported) at 14:00 on 03-Nov-2009. Fifteen minutes later, the patient suddenly experienced lipothymia and collapsed. It was reported that the patient was pale and cyanotic around lips, and lost consciousness for a couple of minutes. Subsequently, the patient was confused for a couple of hours and experienced paralysis of left side and left side headache. It was reported that the patient slept deeply for hours and was admitted to hospital in the afternoon on 03-Nov-2009. Examination revealed paralysis of left lower extremities. It was reported that the patient received treatment with mild antihistamines (no further specified). The next day the patient was recovering. Duration of the hospitalization was not reported. The patient had a medical history of feeling unwell in connection with taking blood samples. The patient had no medical history of feeling unwell in connection with vaccination. The patient was vaccinated with the first dose of GARDASIL (yeast) (intramuscularly, batch number and site of administration not reported) on an unreported date. No adverse reaction was reported.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **370142-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Oct-2008	01-Nov-2008	31	25-Nov-2009	30-Nov-2009	FR	WAES0903USA02696	30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cat scratch disease, Lymphadenopathy

Symptom Text: Information has been received from a health authority (HA ref. DK-DKMA-20090510) concerning a 13 year old female who on 01-OCT-2008 was vaccinated IM with the first dose of GARDASIL. On 01-NOV-2008 the patient developed swollen glands on right groin. The patient was admitted to hospital (date and duration not reported). At the time of the report, the patient was not recovered. Follow-up information received on 12-NOV-2009 from Health Authority. Blood samples taken on 18-MAR-2009 revealed Bartonella Henslae infection. It was reported that swollen glands on right groin was due to Bartonella Henslae infection and not related to the vaccination. Outcome was not reported. Case is closed. No further information is available. Other business partner numbers include E2009-02176.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 18Mar09, blood samples revealed Bartonella Henslae infection

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370232-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	25-Nov-2009	25-Nov-2009	0	25-Nov-2009	27-Nov-2009	TX		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0670Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: While waiting advised 15 min following vaccination pt passed out while in clinic lobby/ waiting area, was taken to treatment room via gurney, and assessed by PCM.

Other Meds:

Lab Data:

History: n/a

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370234-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Nov-2009	11-Nov-2009	0	25-Nov-2009	27-Nov-2009	NC		30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB342AA	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3096AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1013Y	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Patient recieved shot and then faintied and then hit head.

Other Meds:

Lab Data: Patient sent for CT of the Head and to Neuologist

History: none that was noted

Prex Illness: none that was noted

Prex Vax Illns: patient felt faint but did not faint~HPV (Gardasil)~~14.00~Patient

Vaers Id: **370251-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Nov-2009	11-Nov-2009	0	25-Nov-2009	29-Nov-2009	KY		30-Nov-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Fall, Head injury, Pallor, Syncope

Symptom Text: Syncopal episode after Gardasil #1 (pale, clammy, slid to floor?, hit head-easily aroused B/P 105/55 pulse 70). Within 5 min, assisted to chair, sipping soda, lying on fathers shoulder became faint again.... Assisted to exam room/ within 20 min able to sit without dizziness or complaints. Home with father. No complaints best day when follow up call made.

Other Meds: None

Lab Data: None

History: Hx: "childhood asthma"

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 370369-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	08-Aug-2007	02-Oct-2007	55	28-Nov-2009	01-Dec-2009	VA		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0469U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Ataxia, Back pain, Bacterial infection, Balance disorder, CSF test abnormal, Hypoaesthesia, Myelitis transverse, Neck pain, Nystagmus, Paraesthesia, Paralysis, Steroid therapy

Symptom Text: Pt awoke in AM with severe neck and upper back pain. Developed numbness and tingling from shoulders down and then quickly turned into weakness then paralysis from shoulders down. Went to emergency room and diagnosed clinically with T4 transverse myelitis. 12/02/09 DC Summary and hospital records received for DOS 10/02/07-10/08/07. Pt. awoke on morning of 10/02/07 with stiff neck, shooting pain down both arms and progressive weakness of bilateral upper extremities. Admitted to hospital and treated with steroids with initial improvement of left upper extremity weakness. Developed gait ataxia during hospital stay which also improved by discharge. Diagnosed with mycoplasma pneumoniae and infectious disease consult obtained; tx. with antibiotic. Right upper extremity significant weakness remained. Discharged home to continue physical therapy as outpatient. DC DX: Transverse myelitis; positive mycoplasma in serum with CSF 12/02/09 Neurology records received for DOS: 10/12/07, 11/20/07, 06/10/08, 01/01/08, 02/15/2008 Pt. presents with continued numbness of left leg with loss of pain and temperature sensation; persistent weakness of right arm DX: Transverse myelitis; mild lateral gaze nystagmus 12/7/09: Neurology consult received for date of service 12/2/09: Dx: Transverse Myelitis. Full movement of affected arm with continued weakness. No pain. Numbness of left leg to pain. Trouble balancing on right leg at times. mild lateral gaze nystagmus. Assessment: Improved, continue Physical Therapy.

Other Meds: Bactrim

Lab Data: MRI of C-,T-spine and brain initially negative. Repeat MRI 6 days later showed abnormal T2 signal at C2-3 through C5-6 level within cord that were gadolinium enhancing, involved white and grey matter. CSF exam negative, positive mycoplasm

History: ALLER GY TO AMPICILLIN 12/02/09 PMH: amoxicillin alllergy

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370371-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Sep-2009	29-Sep-2009	0	27-Nov-2009	30-Nov-2009	WY		28-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB312AA	0	Left arm	Unknown	
MNQ	SANOFI PASTEUR	U3015AA	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0216Y	0	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Arthralgia, Balance disorder, Delirium, Dizziness, Dysarthria, Eye rolling, Immediate post-injection reaction, Injection site haemorrhage, Pain in extremity

Symptom Text: On Thursday Oct. 1st, I answered the clinic phone for a "question about vaccinations" per front desk. The phone call was from mother. She reported that she brought her 16 year old daughter to hospital for "immunizations." Mother reported that daughter was given Hepatitis A, HPV, and Meningitis vaccine at about 5pm on Tuesday 09/29/09. Mother commented " they talked to me into getting the meningitis one." She said that daughter got "dizzy" right away and had commented that she felt the meningitis shot "in elbow." Mom reported that daughter said her knees hurt on the way home and was rubbing her knees and legs in the car. Mother took daughter to the ER at around 9pm. She said that daughter was "delirious", she "couldn't walk or talk" and her "eyes were rolling back in her head." Mom denies fever, respiratory distress or seizure activity in her daughter at that time. Pt was admitted to hospital on 09/29/09 and kept for 24 hours while "tests" were run. Mother stated that doctor was called in "consult" and that her daughter's MRI showed "fluid in the brain". Her symtomology resolved spontaneously according to her mother, "going backwards" with the last symptoms resolving first and finally the pain in legs, knees, and her arm resolving. Mother said that doctor told her this could only happen if the meningitis vaccine had been give "direct IV". At this time mother is mainly concerned because daughter's arm bled and she didn't know if that meant the shot went into her vein or not. I reassured mother that bleeding from the injection site after an immunization is not uncommon and does not mean that the vaccine accessed the vein. She seemed to be calmer after that, talking a little slower and with less emphasis. I told her I would check with my superior and call her back. Discussed the reaction with PNP. She suggested I file VAERS report and encourage mother to do the same. Called mother at home and asked if she still had the VIS sheets given at time of daughter's vaccinations. She did, I asked her to look at the back of th

Other Meds:

Lab Data: none Labs: CBC, CMP, ESR, coagulation studies, Mono-test, urine pregnancy test all wnl Dx studies: CT head and MRI Brain wnl, EKG noted bradycardia

History: PMH: None Allergies: red dye, codeine

Prex Illness:

Prex Vax Illns:

Vaers Id: **370588-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	16-Nov-2009	16-Nov-2009	0	30-Nov-2009	30-Nov-2009	NC		07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0981Y	1	Left arm	Intramuscular	FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Pt with severe body aches, sudden onset. Sx lasted through the night. Pt took 800mg of Ibuprofen at 8:00AM on 11/17/2009 and sx were better. Completely resolved by the afternoon of 11/17/09.

Other Meds:

Lab Data:

History: NKDA

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370615-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Nov-2009	20-Nov-2009	0	30-Nov-2009	01-Dec-2009	AZ		07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3020AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF551BA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Gave 3rd shot, patient fainted from sitting position on table. Doctor notified . B/P 110/70. Patient rested on table for 15 min until felt better. Left office without difficulty.

Other Meds:

Lab Data:

History: Club foot. Seasonal allergies. amniotic band syndrome.

Prex Illness: HCM

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370618-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	17-Sep-2008	17-Sep-2008	0	30-Nov-2009	01-Dec-2009	CT	WAES0810USA03351	02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Delivery, Drug exposure during pregnancy, Pneumonia

Symptom Text: Information has been received from a nurse, for the pregnancy Registry for GARDASIL, concerning a 21 year old female with a history of a "rash from PERCOCET" who was vaccinated with first (lot # 659182/1757U), second (lot # 660389/1968U) and third (lot # 660557/0072X) doses of GARDASIL on 24-MAR-2008, 28-MAR-2008 and 17-SEP-2008 respectively. There was no concomitant medication. Subsequently the patient was vaccinated with 3 doses of GARDASIL and was pregnant. The patient's last menstrual period was in question but may have been on 06-SEP-2008. The patient was not experiencing any problems. A urine pregnancy test was performed on 13-OCT-2008 and the result was positive. The patient sought medical attention. Follow up information has been received from a certified nurse midwife and a licensed practical nurse concerning a 21 year old female with a history of a "rash from PERCOCET", asthma, appendectomy and no previous pregnancy who was vaccinated with first (lot# 659182/01757U), second (lot# 660389/1968U) and third (lot# 660557/0072X, IM in deltoid) doses of GARDASIL on 24-MAR-2008, 28-MAY-2008 and 17-SEP-2008 respectively. Concomitant therapy included prenatal vitamins (unspecified), daily. The patient did ultrasound on 20-Oct-2008 for dating and the result was 6.5 weeks intrauterine pregnancy. The patient did maternal serum alpha fetoprotein on 19-Dec-2008 and the results was within normal limits. The patient did first trimester screening on 01-Dec-2008 and the result was within normal limits. The patient did ultrasonography on 15-JAN-2009 and the result was 20 weeks intrauterine pregnancy. Follow up information has been received from a certified nurse midwife concerning a 21 year old female tobacco user who was pregnant. Subsequently, in approximately October 2008 the patient developed pneumonia and was treated with AVELOX, 400 mg daily, from 10-OCT-2008 to 17-OCT-2008. On 17-JUN-2009, the patient delivered a normal 5 pound 15 ounce male infant. There were no congenital anomalies or any complications during pre

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 10/20/08, 6.5 weeks intrauterine pregnancy; Ultrasound, 01/15/09, 20 weeks intrauterine pregnancy; Diagnostic laboratory, 12/01/08, first trimester pregnancy; Diagnostic laboratory, 06/22/09, 39 ng/m, cystic fibrosis screen; S

History: Appendicectomy

Prex Illness: Pregnancy NOS (LMP=9/6/2008); Drug hypersensitivity; Tobacco user; Asthma

Prex Vax Illns:

Vaers Id: **370621-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	26-Jun-2008	26-Jun-2008	0	30-Nov-2009	01-Dec-2009	IA	WAES0807USA04523	02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Hydronephrosis

Symptom Text: Information has been received from the pregnancy registry for GARDASIL from a 23 year old female patient, with no pertinent medical history and no drug reactions/allergies, who on 26-JUN-2008, was vaccinated with the first dose of GARDASIL. Concomitant therapy included cephalexin. A few days later after receiving the first dose of GARDASIL, the patient found out she was pregnant. The patient sought medical attention. The last menstrual period was six weeks from 23-JUL-2008 (approximately on 11-JUN-2008). On an unspecified date, was performed a pregnancy test resulting positive. Estimated date of delivery approximately 18-MAR-2009. No adverse reaction was reported. Follow up information received from the patient indicated that on 12-MAR-2009 she gave birth to baby girl. It was reported that the baby had "some problems"; the baby was born with hydronephrosis in her kidneys and had two surgeries. The baby was "doing fine now". Additional information has been requested.

Other Meds: cephalexin

Lab Data: beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/11/2008)

Prex Vax Illns:

Vaers Id: **370627-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		30-Nov-2009	01-Dec-2009	--	WAES0911USA03001	02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Fatigue, Laboratory test, Pancreatectomy, Systemic lupus erythematosus

Symptom Text: Information has been received concerning a female patient "maybe college-age" with unspecified medical history, drug reactions or allergies, who in 2008 was vaccinated with a dose of GARDASIL (route and lot # unknown). Concomitant medication unspecified. On 17-NOV-2009, a news station reported that the patient reported that she received GARDASIL and on an unspecified date she became tired all of a sudden, she also suddenly developed lupus and her pancreas had to be taken out. She possibly might need chemotherapy in the future. Unspecified lab diagnostic studies performed. The patient sought unspecified medical attention. At the time of this report the patient had not recovered. Attempts are being made to verify the existence of an identifiable patient. No further information is available.

Other Meds: unknown

Lab Data: unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370630-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		30-Nov-2009	01-Dec-2009	--	WAES0911USA04136	02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Paralysis

Symptom Text: Information has been received from a medical assistant who heard from a physician's assistant concerning some patients who were vaccinated with unspecified doses of GARDASIL (lot#, route and site of administration not reported). Subsequently, the patients became blind and paralyzed. At the time of this report, the patient's outcome were unknown. Follow up information has been received from a physician's assistant who stated that one of her patients stated that she did not want receive GARDASIL because she had heard someone became paralyzed after receiving GARDASIL. Upon internal review, being paralyzed was considered to be an other important medical event. Attempts to verify the existence of an identifiable patient have been unsuccessful. This is one of several reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **370632-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
33.0	F	07-Feb-2009	Unknown		30-Nov-2009	01-Dec-2009	FR	WAES0903USA05371	02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: This is a case of pregnancy misuse (off label use, 33-year-old female vaccinated with a vaccine indicated for women under 26 years old). Initial information received on 10-MAR-2009 by a consumer, regarding his wife, for the pregnancy registry of GARDASIL. The 33-year-old female patient who was vaccinated on the 07-FEB-2009 with the second dose of GARDASIL (batch# and site not reported). It was reported that shortly after vaccination, the patient found out that she was pregnant, probably since the 14-FEB-2009. LMP date was 29-JAN-2009 and the patient was administered the vaccine on 07-FEB-2009. No adverse events have been reported. The patient has had a previous pregnancy. It is reported that the patient gave birth to a healthy child. Further information received from the patient's husband reported that on 19-JUN-2009, a high definition sonogram was performed with 20 weeks gestation with normal results. Next appointment with gynaecologist was scheduled on 30-JUN-2009. On 01-JUL-2009, the reporter was contacted again. Finally the appointment with gynaecologist was scheduled on the 02-JUL-2009. Further information reported by the patient's husband reported that the patient went to the social security gynaecologist, as scheduled, in mid July 2009. According to the reporter she was expecting a healthy male baby. Additional information was received from the patient's husband who reported the results of the blood work performed three weeks ago were normal. The result of the glucose screening test performed was also normal. It has been reported that delivery was expected on 04-NOV-2009. Follow-up information was received from the patient's husband who reported that the patient gave birth, without fetal suffering on 05-NOV-2009 a healthy male baby, 3.500 kg, 49 cm, 1 minute Apgar test score 09, 5 minute Apgar test score 10. The baby was born by cesarean section without postnatal complications. Upon internal review cesarean section was considered to be an other important medical event. Other business partner numbers includ

Other Meds: Unknown

Lab Data: ultrasound, 19Jun09, with 20 weeks gestation with normal results; diagnostic laboratory test, 12Aug09, blood test, normal; plasma glucose screen, 12Aug09, normal

History: Pregnancy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370681-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Jun-2008	13-Aug-2008	62	30-Nov-2009	01-Dec-2009	CA		06-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Patient claims that after Gardasil. Her periods have not been on time.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370771-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Dec-2007	12-Jul-2008	206	01-Dec-2009	01-Dec-2009	KY		30-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1266U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Antibiotic therapy, Deep vein thrombosis, Feeling cold, Feeling hot, Hyperaesthesia, Lymphadenitis, Oedema peripheral, Paget-Schroetter syndrome, Pain in extremity, Paraesthesia, Thoracic outlet syndrome

Symptom Text: 07/12/2008 presented to doctor office with hx 5 days of "Right arm aching/swelling". Diagnosis? Rt. axillary adenitis placed on KEFLEX 500 mg tid. No known Hx trauma. Has sensation to touch/heat/cold etc.; yet "tingly". Dx DVT and Paget Schroetter syndrome Aug 08. I called Mom this evening to discuss further her question regarding patient's Gardasil vaccine series and her n/o blood clot. Patient has had something called Paget Schroetter syndrome which is a subset of thoracic outlet syndrome. This is usually due to inadequate space for the subclavian vein to run through at the shoulder due to anatomic variations in the 1st rib and clavicle (thus causing blood clot) or can also be from anterior scalene hypertrophy from repetive UE use. Patient used to participate in karate so this possibly may have put her at risk for this. I also reviewed office visit notes. I also reviewed the time course of patients Gardasil vaccines. Her initial visit here for RUE swelling was 6-7 mos following her 3rd Gardasil vaccine. I researched Gardasil and blood clots over the weekend and most of the alleged cases of causality are in clots that occurred within days to weeks following Gardasil vaccine. I reviewed this w/Mom and advised that, given the cause of patient's clot being an anatomic etiology, and the fact that her Gardasil series was several months prior to her blood clot, I don't think the two are related. However I again emphasized that we may never know the true answer and I am only relating my observations based on my research into Paget Schroetter Syndrome and Gardasil/blood clots. Mom said she was relieved to hear this, I think she was experiencing alot of guilt for having patient complete the Gardasil series, in light of the complications patient has had from surgery for the aforementioned syndrome (had a pneumothorax as a complication from surgery to remove part of a rib to make room for her R subclavian vessel). I also disc'd the VAERS reporting service and advised that we would submit patient info to them which may hel

Other Meds: ALLEGRA 60 mg daily

Lab Data: 07/17/08 Cat Scan chest negative Labs: CBC, CMP, Uric acid, LDH, Anticardiolipin AB all WNL, PT elevated Dx studies: CT chest normal, Doppler study RUE abnormal + for DVT

History: Seasonal allergic Rhinitis PMH: Seasonal allergies Rhinitis Allergies: NKDA

Prex Illness: Well child visit

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370776-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Feb-2009	11-Feb-2009	0	01-Dec-2009	02-Dec-2009	FR	WAES0905USA01428	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0055X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information has been received from a physician via CSL as part of a business agreement (manufacturer control # 20090513JV1) concerning a 15 year old female patient who on 10-JAN-2009 had her last menstrual period and then on 11-FEB-2009 received the first dose of GARDASIL (Lot not reported), and on 12-MAY-2009 received the second dose of GARDASIL (Lot not reported). Subsequently the patient was found to be pregnant. The patient's estimated date of delivery is 17-OCT-2009. Follow up information has been received from the physician via Pregnancy Questionnaire, concerning the patient who on 11-FEB-2009 was vaccinated with the first dose of GARDASIL (Lot number659659/0055X and Batch number K3111) and on 11-MAY-2009 (previously reported as 12-MAY-2009) with the second dose of GARDASIL (Lot number 660614/0241X and Batch number K2557). The vaccination occurred 4.5 weeks and 17.5 weeks after the last menstrual period. The pregnancy was confirmed by a clinical ultrasound. The patient did not had previous pregnancies. It was reported that the patient had excess alcohol use until pregnancy discovered. Follow up information was received which reported that the patient on an unknown date underwent a ultrasound which showed she was 18 weeks and 5 days. It was reported that the patient did not have infections/illness during pregnancy, did not take prescriptions drugs and did not have complications during pregnancy, labor or delivery. On 15-OCT-2009, the patient delivered a normal male child weight at 10 days of age was 3.2 Kg (birth weight not provided). The infant was born with a hypospadias, there were no other complications reported. It was reported that the discharge summaries were not available. Additional information has been requested.

Other Meds: unknown

Lab Data: ultrasound, 18 weeks and 5 days

History:

Prex Illness: Pregnancy NOS (LMP = 10Jan09); alcohol use

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370779-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Aug-2009	01-Aug-2009	0	01-Dec-2009	02-Dec-2009	FR	WAES0911PHL00033	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning an approximately 25 year old female who in June 2009, was vaccinated with first dose of GARDASIL. The second dose was received on August 2009. There were no concomitant medications at the time of the vaccination. In approximately August 2009, the patient experienced an adverse effect. The patient consulted with a rheumatologist and was advised that she experienced drug induced SLE. Subsequently, the patient recovered from drug induced SLE. The patient refused to receive the third dose due to the event. The relationship of drug induced SLE to therapy with GARDASIL was unknown by both the rheumatologist and the reporter. The rheumatologist, however, advised the patient that although SLE can caused by other factors, drug induced SLE may be ascribed to the vaccine. The patient requested the reporter for a certification that she received two doses of the suspect therapy. Upon internal medical review, drug induced SLE was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370780-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Jun-2009	13-Jul-2009	34	01-Dec-2009	02-Dec-2009	FR	WAES0911USA02561	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0153X	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Arthritis, Movement disorder

Symptom Text: Information has been received from a Health Authority under the reference number LY20091042 AM0910017, concerning a 17 year old female patient, described as an "adolescent in crisis", with psychiatric history but not treated, and with a difficult medical follow up, had received the first dose of GARDASIL (lot number 0153X, batch number NJ14700) via intramuscular route on 09-jun-2009. On 13-JUL-2009 she was hospitalized due to a violent pains in the right hip and a functional impairment. The presence of an articular effusion was noticed. Hip arthritis was diagnosed. The patient was given analgesics and anti-inflammatories, and was prescribed rest. Painful sedation was obtained. The patient was discharged on 16-JUL-2009, with a prescription of rest. The second dose of GARDASIL was planned in OCT-2009, but it was cancelled as the pain in the hips was still present. The following biological work-ups were performed: 13-JUL-2009: accelerated ESR, polynucleosis. 15-JUL-2009: erythrocyte serum in culture showed the absence of germs. 02-NOV-2009: Blood count and differential white count was normal, antinuclear antibodies were negative, c-reactive protein was normal and ESR was at 21. At the time of the report the patient was recovering. The health authority assessed the causal relationship between the reported events and the vaccination as "doubtful" (C2, S1, I1) according to the method of assessment. Other business partner numbers include E2009-10613. No further information is expected.

Other Meds: Unknown

Lab Data: red blood cell scan, 13Jul09, Blood count: normal; erythrocyte sedimentation rate, 13Jul09, accelerated ESR, polynucleosis; blood culture, 15Jul09, erythrocytic serum: absence of germs; WBC count, 02Nov09, normal; serum ANA, 02Nov09, negati

History:

Prex Illness: Psychological disorder NOS

Prex Vax Illns:

Vaers Id: **370782-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	27-Mar-2009	01-Apr-2009	5	01-Dec-2009	02-Dec-2009	FR	WAES0909USA05014	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1068U	0	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abnormal faeces, Decreased appetite, Diarrhoea, Dizziness, Dry mouth, Dyspepsia, Gastric disorder, Gastroenteritis, Gastrooesophageal reflux disease, Irritable bowel syndrome, Mucous stools, Nausea

Symptom Text: Information has been received from a healthcare professional on 17-SEP-2009. Case additional received from Health Authority (reference # PEI200902051) on 23-SEP-2009. It was reported by a gynaecologist that a 24 year old female was vaccinated with a first dose of GARDASIL (lot #1068U, batch #NH06410, route not reported) into the left upper arm on 27-MAR-2009, the second dose (lot #1427U, batch #NH17960) into the left upper arm on 25-MAY-2009. On an unspecified date in April 2009, the patient developed anorexia, dry mouth, abnormal stools with mucous stools, dizziness and relapsing nausea. Colonoscopy and gastroscopy showed no pathological findings. Neurologic psychiatric examinations were planed. Unspecified treatment was carried out. At time of report, symptoms were still ongoing. Follow-up information received on 18-NOV-2009. Several examination reports were provided. The case has to be updated due to hospitalization of the patient. Since beginning of June 2009 the patient complained of typical signs of gastroesophageal reflux disease. Under treatment with omeprazol symptoms did not improve. On 24-JUN-2009 a gastroscopy was carried out and showed no pathological findings. The diagnosis of "non-erosive reflux disease" was established. Histological examination showed normal results. On 11-JUL-2009 the result of a stool sample showed no evidence of salmonella, shigella, yersiniae and campylobacter. On 21-JUL-2009 a coloscopy was carried out and also showed normal results. No histological findings in iliac mucosa. On 07-AUG-2009 a thoracic radiological imaging was carried out and showed normal results for heart and lung. From 09-JUL-2009 to 10-JUL-2009 the patient was hospitalized because of changing stools and mucous diarrhea. A non-infectious gastroenterocolitis was diagnosed. The patient was treated with spasmolytics and not specified infusional therapy and recovered quickly. On 28-AUG-2009 a blood sample was taken and showed following normal result for gliadin antibodies in serum: Gliadin IgA 1.1 u/ml (normal:

Other Meds: Unknown

Lab Data: Gastroscopy, 24Jun09, no pathological findings; Diagnostic pathological examination, 24Jun09, normal results; Colonoscopy, 21Jun09, no pathological findings; Abdominal ultrasound, 28Aug09, no pathological findings; Gastroscopy, 04Sep09, no

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370783-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Jun-2009	01-Jul-2009	26	01-Dec-2009	02-Dec-2009	FR	WAES0911USA04467	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blindness, Blood product transfusion, No reaction on previous exposure to drug, Optic neuritis

Symptom Text: Information has been received from a gynecologist concerning a 15 years old female patient who was vaccinated with a third dose of GARDASIL (lot number: 1427U, batch number: NH15200) into the left upper arm on 05-JUN-2009, route not reported. In Jul 2009 the patient developed optic neuritis with loss of vision. The patient was hospitalized on an unspecified date. Symptoms improved after the patient was treated with plasmapheresis but the patient had not recovered at the time of reporting. The first and second dose of GARDASIL (lot number: 1427U, batch number: NH15200), administered IM into the left upper arm on 05-DEC-2008 and on 05-FEB-2009 were well tolerated. Other business partner numbers include E2009-10729. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370785-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Apr-2009	01-Oct-2009	183	01-Dec-2009	02-Dec-2009	FR	WAES0911TWN00009	25-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Carcinoma in situ, Cervical conisation

Symptom Text: Information has been received from a female who in April, June and October 2009, was vaccinated with the three doses of GARDASIL vaccines. In September 2008, the patient's cervical smear was normal, but in October 2009 (on the same day she received the 3rd dose of GARDASIL vaccine), the patient's cervical smear showed carcinoma in situ. Then the patient received cervical conization. Subsequently, in November, the patient recovered from carcinoma in situ. No further information is available.

Other Meds: Unknown

Lab Data: cervical smear, ??Sep08, normal; cervical smear, ??Oct09, carcinoma in situ

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **370786-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	02-Oct-2007	09-Nov-2009	769	01-Dec-2009	02-Dec-2009	TN	WAES0911USA04285	14-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	89620	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Amnesia, Anxiety, Blood test, Chills, Convulsion, Depressed mood, Diarrhoea, Dysmenorrhoea, Gastroenteritis, Headache, Migraine, Vomiting

Symptom Text: Information has been received from a consumer concerning her 29 year old daughter with "allergies of many unspecified medications" and no pertinent medical history, who was vaccinated with "all three doses" of GARDASIL, respectively on 29-MAR-2007, 29-MAY-2007 and 02-OCT-2007. There was no concomitant medication. On 09-NOV-2009 the patient experienced "seizures". Labs and diagnostic tests included "routine blood work", result not reported. The patient visited physician for medical attention and had not recovered. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested. 12/07/09 ED received for DOS 12/01/09 DX: Gastroenteritis. Pt c/o vomiting and diarrhea and unable "to keep anything down". On examination: anxious, chills, depressed and abdominal pain. tx: Zofirax. Pt discharged home. ```records received 12/28-29/2009 OB-GYN records 3/2007-10/2007 , PCP records and Neuro consult for 10/14 and 11/9/2009 , the OB records reported Gardisil injections but no lot or manufacturer, PCP records reflected c/o's dysmenorrhea. Neuro consult for ? seizure activity noted patient with c/o's memory loss and headaches, thought to be migraines with negative dx studies, was started on Topamax

Other Meds: None

Lab Data: 12/07/09 ED received for DOS 12/01/09 DX studies: Pain rating 4/10. CBC: negative. ```records received 12/28-29/2009 OB-GYN records 3/2007-10/2007 , PCP records and Neuro consult for 10/14 and 11/9/2009 Dx studies: MRI, MRA brain and

History: 12/07/09 ED received for DOS 12/01/09 PMH: Neurocardiogenic syncope, appendectomy and cholecystectomy; Allergies: Cefactor caps, IV dyes, latex, PCN, Unasyn. ```records received 12/28-29/2009 OB-GYN records 3/2007-10/2007 , PCP records and Neuro consult for 10/14 and 11/9/2009 PMH: Learning disability

Prex Illness: Hypersensitivity ```records received 12/28-29/2009 OB-GYN records 3/2007-10/2007 , PCP records and Neuro consult for 10/14 and

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370882-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	23-Nov-2009	23-Nov-2009	0	01-Dec-2009	02-Dec-2009	CA		07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3069AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Syncope, Vision blurred

Symptom Text: 5 minutes after injections patient states she had blurred vision and nausions and patient had syncope. Patient had full recovery by 10:40.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370889-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Nov-2009	23-Nov-2009	0	01-Dec-2009	02-Dec-2009	FL		07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainted 5 min after HPV vaccine in our office.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370894-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Nov-2009	Unknown		01-Dec-2009	03-Dec-2009	MN		05-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pregnancy test positive

Symptom Text: Pt was given GARDASIL #2 on 11-17-09. She returned to the clinic on 11/23/09 & had a positive Pregnancy test.

Other Meds: None

Lab Data: Positive UHCG on 11-23-09

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **370999-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Nov-2009	19-Nov-2009	0	01-Dec-2009	02-Dec-2009	PA		02-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U3207AA	1	Right arm	Unknown	
	HEPA	MERCK & CO. INC.	0913Y	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3070AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainted

Other Meds:

Lab Data: Pt had CT scan of the head following visit

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371167-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	23-Apr-2009	Unknown		02-Dec-2009	03-Dec-2009	--	WAES0907USA00896	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Stillbirth

Symptom Text: Information has been received from an investigator concerning a female who entered a study, title as stated above. On 23-APR-2009 was vaccinated with the first dose of GARDASIL (LOT# not reported). The patient's last menstrual period was last week of April 2009. The pregnancy is normal to date. Patient will be followed by study, but not receive any other doses of GARDASIL. Follow-up information was received from a caller who wanted to report a pregnancy registry for a clinical trial for GARDASIL. Unable to confirm information. In the follow-up the investigator stated they were no longer giving the patient GARDASIL and asked if it would be okay to only report the information to their contact for the clinical trial and if they need to call again. In the follow-up the investigator stated that the patient who had been approximately 28 weeks pregnant had a stillbirth on 21-NOV-2009. The relationship between the stillbirth at 28 weeks and GARDASIL was not reported. Upon internal review stillbirth at 28 weeks was considered to be an other important medical event. No further information was reported.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 4/25/2009)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371168-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Dec-2009	03-Dec-2009	FR	WAES0911USA04463	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Henoch-Schonlein purpura, Vasculitis

Symptom Text: Case received from a health care professional in a foreign country on 19-NOV-2009. The case is poorly document. It was reported from a physician who had the information from a colleague that an adolescent female patient was vaccinated with the first dose of GARDASIL (Lot#, injection route and site not reported) on an unspecified date. A few days post vaccination, the patient was diagnosed with purpura Schoenlein-Henoch with involvement of joints (not otherwise specified). The patient was hospitalized several times and the final diagnosis was reported to be vasculitis. The company was contacted to enquire if the case had already been reported. Other business partner numbers include E2009-10724. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **371169-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Oct-2008	01-Feb-2009	94	02-Dec-2009	03-Dec-2009	FR	WAES0911USA04465	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1145U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Condition aggravated, Cough, Headache, Iron deficiency anaemia, Joint stiffness, Lupus nephritis, Nasopharyngitis, Pleurisy, Pyrexia, Renal impairment, Steroid therapy, Systemic lupus erythematosus

Symptom Text: Initial case was reported as serious on 19-NOV-2009 by Health Authority (093799). It was reported that a 16-year-old girl was vaccinated with the second (batch number NH01650, Lot # 1145U, route and dose not reported) and the third dose (batch number NJ03220, i.m. route 0.5 ml) of GARDASIL on 29-DEC-2008 and 05-MAY-2009 respectively. HA coded SLE (systemic lupus erythematosus) (causality unclassifiable due to no supporting documentation of a causal relationship except for a relationship in time) with onset on unspecified date in June 2009. In February 2009 the girl went to the doctor due to recurrent headache. Iron deficiency anemia was established and DUROFERON (GSK) was prescribed as treatment. At the end of April 2009, prior to vaccination with dose three, the girl caught a cold with fever and non productive cough. Shortly after vaccination with the third dose the girl experienced arthralgia in hands, finger and knees. Progressive problems with joints (stiffness), kidney dysfunction and affected hematology (no details specified) quickly followed. Investigation at the hospital established SLE and SLE-nephritis stage III based on her symptoms (not specified which) in combination with a positive ANA test and pulmonary X-ray that showed left sided pleurisy. The patient is put on treatment with CELLCEPT (mfr Roche) and steroids (not specified, mfr unknown). No adverse event was reported following vaccination with dose of GARDASIL on 30-OCT-2008 (Batch # NH01650, lot #1145U). The outcome is not yet recovered. No further information is available. Case is closed. Systemic lupus erythematosus was considered to be an other important medical event. Other business partner numbers include E2009-10760.

Other Meds: Unknown

Lab Data: chest X-ray, ??09, pulmonary x-ray showed left sided pleurisy; serum ANA, ??09, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **371170-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Nov-2009	20-Nov-2009	0	02-Dec-2009	03-Dec-2009	WA	WAES0911USA04557	14-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Activities of daily living impaired, Dizziness, Electrocardiogram ambulatory, Palpitations, Ventricular extrasystoles

Symptom Text: Information has been received from a cardiologist and a receptionist concerning a 17 year old female with no pertinent medical history or drug reactions/ allergies who on 20-NOV-2009 was vaccinated with a dose of GARDASIL. Concomitant therapy included SEASONALE. The patient was nasally vaccinated on 19-NOV-2009 with H1N1. The reporter mentioned that on 20-NOV-2009 the patient received GARDASIL and within minutes could not walk out of the office. It was stated that the patient had premature ventricular contractions. The physician felt a significant disability was the patient "can not drill team". The receptionist stated that the patient was a new patient of the cardiologist and was first seen on 24-NOV-2009. The patient sought a physician in office for medical attention. The patient had the following lab/diagnostics tests: CBC, telemetry, PSH and troponin all of which were normal. At the time of reporting the patient had not recovered. The physician considered the patient unable to walk out of the office, premature ventricular contractions and can't drill team" as disabling. Additional information has been requested. 12/3/2009 Cardio Consult records for 11/24/2009, patient seen for c/o's palpitations and lightheadedness. EKG done at PCP office was abnormal noting PVC's, Tx Holter monitor, recommended addition of fish oil and magnesium

Other Meds: SEASONALE

Lab Data: complete blood cell, Normal; serum troponin, Normal Labs: TSH and Troponin neg Dx studies: EKG abnormal

History: None PMH: None Allergies: Ceclor

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371216-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Nov-2009	03-Nov-2009	0	02-Dec-2009	03-Dec-2009	TX	TX090089PU	20-Jan-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0672Y	2	Left arm	Intramuscular	
HEPA	MERCK & CO. INC.	0605Y	0	Left arm	Intramuscular	
FLUN	MEDIMMUNE VACCINES, INC.	500733P	0	Unknown	Unknown	
FLU(H1N1)	SANOFI PASTEUR	UP010AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Oedema peripheral, Rhinorrhoea, Sneezing, Swelling face, Urticaria

Symptom Text: RECEIVED 3:00 PM IV 3/09. LATER IN THE EVENING RUNNING NOSE, ALLERGY SYMPTOMS 6:00 PM. 11/4/09 1:00 AM NEXT MORNING, WOKE UP WITH SWOLLEN FEET AND TOES. SWOLLEN FACE AND PUFFINESS AROUND JAM AND CHECK AND NOSE. SNEEZING. ON NECK AROUND COLLAR AREA HAD HIVES. SELF TREATED WITH BENADRYL AND CALLED POISON CONTROL THAT MORNING.

Other Meds: SITUAFEN, ZYRTEC

Lab Data: NONE

History: PRE-EXISTING SEASONAL ALLERGY, HAY FEVER

Prex Illness: NONE

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371242-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Nov-2009	23-Nov-2009	0	03-Dec-2009	03-Dec-2009	GA		03-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	06724	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Syncope immediately after vaccine administration.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **371256-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	11-Jun-2009	10-Jul-2009	29	03-Dec-2009	03-Dec-2009	NY		31-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF460CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Altered state of consciousness, Aura, Confusional state, Convulsion, Dizziness, Tongue biting

Symptom Text: Date of GARDASIL injection #1: 6/11/09. Date of seizure: 7/10/09. Correlation unclear: See Neurologist visit note attached from 11/16/09. 12/03/09 Neurology Consult record received DOS 11/16/09. DX: Generalized seizure with aura of confusion 07/10/09; transient alteration of awareness mid-August 2009, duration 1-2 minutes. Pt. to discontinue anti seizure meds since no seizure recurrence. 12/07/09 Neurology records received for DOS 11/17/09, 08/24/09, 10/05/09, 11/16/09. Pt. reports episode of dizziness, confusion, tongue biting, arm waving, loss of awareness on 07/10/09. Episode of eyes fluttering, staring off into space, loss of awareness on 08/10/09. Reports no further seizures, loss of awaremess on 10/05/09. Impression: generalized seizure with aura of confusion; transient alteration of awareness, seizure may have been provoked by gardasil.

Other Meds: SPRINTEC 28

Lab Data: See Neuro letter. Maternal grandfather had epilepsy.

History: 12/03/09 PMH: NKDA, migraine headaches, anxiety, depression.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371283-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		03-Dec-2009	04-Dec-2009	FR	WAES0911POL00013	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Congenital anomaly, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician concerning a female who in approximately 2009 was vaccinated with all three doses of GARDASIL. About one month after third dose of vaccine the patient experienced drug exposure during pregnancy. Pregnancy ultrasound revealed congenital anomalies of the fetus - one leg is shorter, one hand without fingers. The physician is not sure if congenital anomaly was related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Ultrasound, 09?, anomaly- one leg is shorter, one hand without fingers

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371285-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
38.0	F	01-Jun-2009	01-Oct-2009	122	03-Dec-2009	04-Dec-2009	IL	WAES0911USA04742	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Neoplasm malignant, Papilloma viral infection, Vulvovaginal human papilloma virus infection

Symptom Text: Information has been received from a physician concerning a 38 year old female with no medical history or drugs allergies, who in April 2009, was vaccinated with a 0.5 mL first dose of GARDASIL. In June 2009 the patient received a second dose of GARDASIL. There was no concomitant medication. The patient had a routine pap smear in October 2009 which came back positive for HPV in the cervical area and condyloma in vaginal area and were considered to be cancer. The patient received laser treatment as an outpatient. The patient sought unspecified medical attention. At the time of this report the patient was recovering. Upon internal review pap smear positive for HPV and condyloma were determined to be an other important medical events. Additional information has been requested.

Other Meds: None

Lab Data: Pap test, 10/??/09, HPV positive

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 371286-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Feb-2009	01-Aug-2009	157	03-Dec-2009	04-Dec-2009	FR	WAES0911USA04843	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Decreased appetite, Fatigue, Nausea, Weight decreased

Symptom Text: Information has been received from a physician on 23-NOV-2009 concerning an 18 year old female patient who on 25-FEB-2009 was vaccinated with the first dose of GARDASIL (lot# and site of administration not reported). She received the second dose and the third dose of GARDASIL (lot# s and sites of administration not reported) on 24-APR-2009 and late AUG-2009 respectively. Concomitant therapy included hormonal contraceptives (unspecified). At the beginning of AUG-2009, date before the third vaccination, the patient experienced significant fatigue, nausea followed by anorexia with loss of weight from 51kg to 47.5kg ie loss of 3.5kg in three months. After the third dose, the patient was still loosing weight. No myalgia, diarrhea, lymph node or tachycardia were observed. In AUG-2009 complete blood count, transaminases and C-reactive protein (CRP) were normal. In Nov-2009, complete blood count, CRP, serologies for toxoplasmosis and infectious mononucleosis and liver parameters were normal. The patient should be hospitalized in the following days (week 48) to perform additional work-up to explore the loss of weight. At the time of this report, the patient had not yet recovered. The patient's adverse events were considered to be other important medical events. Other business partner numbers included: E2009-10881. Additional information has been requested.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: serum C-reactive protein, ??Aug09, normal; complete blood cell count, ??Aug09, normal; serum C-reactive protein, ??Nov09, normal; complete blood cell count, ??Nov09, normal; Toxoplasma antibody screen, ??Nov09, normal; serum Epstein-Barr vi

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371287-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Oct-2009	30-Oct-2009	0	03-Dec-2009	04-Dec-2009	FR	WAES0911USA04847	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a Health Authority (reference number Es-AGMED-516111333) concerning a 14 year old female patient who was administered on 30-OCT-2009 a dose of GARDASIL (batch number not reported) by intramuscular route (site of administration not reported). It was reported that on the same day of vaccine administration, 30-OCT-2009, the patient experienced convulsion and syncope that lasted 5 minutes. The patient recovered on the same day. No further information was reported. Syncope and convulsion were considered to be other important medical events by the Health Authority. Other business partner numbers included: E2009-10953.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **371288-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Nov-2009	Unknown		03-Dec-2009	04-Dec-2009	FR	WAES0911USA04850	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Angioedema, Eye swelling, Lip swelling, Pruritus generalised, Swelling face

Symptom Text: This case was initially reported by the health authority on 24-NOV-2009. ADR 20529946. Information has been received from a health professional concerning a 17 year old female patient with no known prior allergies who on 12-NOV-2009 was vaccinated intramuscularly with a dose of GARDASIL (lot# and site of administration not reported). On an unspecified date, the day after having the vaccination in school, the patient had woken up with facial, periorbital and lip swelling, and widespread itching. The reporter stated that the events implied a significant allergy to GARDASIL. On an unspecified date, the patient recovered. The reporter considered the events to be serious as they were medically significant. The agency coded the events angioneurotic oedema, facial swelling, itching generalized, lip swelling and periorbital swelling. Case is closed. Other business partner numbers included: E2009-10879. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **371289-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Aug-2009	31-Aug-2009	19	03-Dec-2009	04-Dec-2009	FR	WAES0911USA04890	25-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Optic neuritis, Visual impairment

Symptom Text: Information has been received from the health authority (HA) under the reference number MA20091961 concerning a 16-year-old female patient who had received the second dose of GENHEVAC B (batch number not reported) on 03-JUL-2009 and the second dose of GARDASIL (batch number not reported) on 12-AUG-2009 and in late August 2009, she experienced the first signs of retrobulbar optic neuritis. Retrobulbar optic neuritis was diagnosed on 12-NOV-2009. The Health Authorities coded also subjective visual disturbances as manifestation. Cerebral MRI was normal. The patient had received the first dose of GENHEVAC B (batch number not reported) on 23-APR-2009 and the first dose of GARDASIL (batch number not reported) on 25-MAY-2009. The patient had a family history of epilepsy in a sister and mental retardation in another sister. The Health Authorities assessed the causal relationship between the reported reaction and vaccination as "doubtful" (C1 S1 I1) according to the method of assessment. The patient's optic neuritis retrobulbar was considered to be an other important medical event. Other business partner numbers include E2009-10982.

Other Meds: GENHEVAC B, 23Apr09; GENHEVAC, 03Jul09

Lab Data: magnetic resonance imaging, Cerebral: normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371293-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Jul-2008	01-Aug-2008	4	03-Dec-2009	04-Dec-2009	PA	WAES0809USA04888	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0527X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician through the pregnancy registry for GARDASIL, concerning a 17 year old female patient with no know drug allergies who on 28-JUL-2008 was vaccinated with the first dose of GARDASIL (Lot #660391/0063X) IM 0.5 mL. On 29-SEP-2008, the patient was vaccinated with the second dose of GARDASIL (Lot 661442/0527X) IM 0.5 mL. Concomitant therapy included YAZ. The physician reported that the patient was pregnant. No adverse effect was reported. The patient not had any labs test done. The patient's LMP was 01-AUG-2008 and EDD 08-MAY-2009. The patient sought medical attention at office visit. There was no product quality complaint. Follow-up information was received from a certified physician's assistant who reported that the patient had a spontaneous abortion 1 week following vaccination (approximately on 06-Oct-2008). Upon internal review "spontaneous abortion" was considered an other important medical event. Additional information is expected.

Other Meds: YAZ

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP= 8/1/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371296-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Jan-2009	19-Jan-2009	0	03-Dec-2009	04-Dec-2009	FR	WAES0903USA00320	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a gynaecologist via SPMSD concerning a 15-year-old female patient who was vaccinated with a first dose of GARDASIL (lot#, injection route and site not reported) on 19-JAN-2009. On 19-JAN-2009 pregnancy test was negative. Pregnancy test was positive now. Her last menstrual period was mid of Dec- 2008. The reporter assumed that GARDASIL was vaccinated during early pregnancy. No adverse effect was seen at the time of reporting. The estimated end of pregnancy will be on 08-Oct-2009. Follow-up information received on 27-NOV-2009. Case was upgraded due to pregnancy termination. Information received by a phone call with the reporting physician. A voluntary termination of pregnancy was performed in 11th week of gestation due to personal reasons and the juvenile age of the patient. Up to this time the course of pregnancy was normal. Pregnancy termination and drug exposure during pregnancy were considered to be other important medical events. Case is closed. Other business numbers include E2009-01146.

Other Meds: Unknown

Lab Data: beta-human chorionic gonadotropin (unsp), 19Jan09, negative; beta-human chorionic gonadotropin (unsp), positive

History:

Prex Illness: Pregnancy NOS (LMP = 15Dec08)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371297-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	04-Aug-2009	20-Aug-2009	16	03-Dec-2009	04-Dec-2009	--	WAES0910USA01001	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Anaemia, Drug exposure during pregnancy, Pregnancy

Symptom Text: Information has been received from a 24 year old female patient, for the Pregnancy Registry for GARDASIL, who on 04-AUG-2009 was vaccinated with a first dose of GARDASIL (route and lot # unknown). On approximately 20-AUG-2009, the patient became pregnant after receiving GARDASIL. The LMP was on approximately 20-AUG-2009 and EDD was on approximately 27-MAY-2010. The patient sought unspecified medical attention. At the time of this report the patient's outcome was unknown and the patient had 7 weeks gestation. Follow up information has been received from the nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning the 24 year old female (patient 4 of 4) without pertinent medical history, no drug reactions or allergies reported, who on 04-AUG-2009 was vaccinated with a 0.5 mL first dose of GARDASIL, intramuscular route (lot # unknown) No concomitant medication. The patient elected to abort the pregnancy on 19-OCT-2009. There was no congenital anomaly known related to the baby. The patient also experienced anemia related to the abortion. The nurse practitioner reported that this was the second patient's abortion and it was determined that she was RH negative and she was treated with RHOGAM. The LMP was on 21-AUG-2009. Additional lab diagnostic studies performed were unspecified. The patient sought medical attention at the physician's office. At the time of the report the patient was fine. Upon internal review, the abortion was considered to be an other medical event of medical importance. Additional information has been requested.

Other Meds: None

Lab Data: erythrocyte Rhesus, RH negative

History: Abortion

Prex Illness:

Prex Vax Illns:

Vaers Id: **371336-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Mar-2007	11-Apr-2008	399	03-Dec-2009	04-Dec-2009	OK		30-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426 F	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U1878AA	0	Right arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Lumbar puncture, Optic nerve disorder, Papilloedema, Visual acuity reduced, Visual field defect, Visual impairment

Symptom Text: VISION PROBLEMS, SWOLLEN OPTIC NERVE, PAPILLEDEMA. WENT TO SPECIALISTS AND STARTED TESTING. HAD EYE EXAMS, ULTRASOUNDS OF EYES, SPINAL TAP, MRI, BLOOD WORK AND VISUAL FIELD. POSSIBLE OTHER TEST 12/04/09 Opthalmology records received for DOS 04/11/08-09/19/08. Pt. presents with difficulty with hand work x 1-2 weeks DX: papilledema 12/04/09 Medical records received for DOS 04/11/08, 04/16/08, 04/18/08, 04/29/08 12/04/09 Neuro-opthalmology records received for DOS 06/18/08 DX: visual fields enlarged blind spot, right eye; bilateral optic nerve drusen 12/04/09 PCP records received for DOS 03/09/07-07/10/09.

Other Meds:

Lab Data: SPINAL TAP, BLOOD WORK, MRI, VISUAL FIELD AND ULTRASOUNDS AND BAYBE OTHERS 12/04/09 Labs/Diagnostics: MRI brain: normal; AB Bartonella: negative; Free T4: 0.73 (L); ANA: not detected; WBC 13.6 (H); CSF culture: rare WBCs; Ultrasound optic

History: NO 12/04/09 PMH: right knee plica; sinusitis; acne; NKDA.

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **371343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Dec-2009	Unknown		03-Dec-2009	04-Dec-2009	TN		08-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0669Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Chills, Myalgia, Nausea, Pyrexia, Vomiting

Symptom Text: 12/01/09 6:30 pm chills, subjective fevers, 2 episodes of nausea and vomiting with myalgias and arthralgias. 12/02/09 Awoke with fever 100.4. 12/02/09 Appointment in clinic 8:55 am /no further nausea or vomiting, feels better injection site no erythemia or exudate nontender. T 97.6. Plan rest, push fluids, Tylenol, return as needed.

Other Meds: Citalopram 10 mg qd; Loestrin 24 FE daily; Pyridium 200mg as needed

Lab Data:

History: Anxiety

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371391-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Dec-2009	03-Dec-2009	0	03-Dec-2009	04-Dec-2009	TX		04-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU(H1N1)	SANOFI PASTEUR	UP044AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB312AA	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	NULL	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypoacusis

Symptom Text: Client felt light-headed and had to be helped to the ground. She described not being able to hear very well and a faint feeling.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: fainting~HPV (no brand name)~1~15.00~Patient

Vaers Id: 371392-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Nov-2009	29-Nov-2009	27	03-Dec-2009	04-Dec-2009	OR		12-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575-X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain lower, Apnoea, Ataxia, Blood pressure decreased, Blood product transfusion, Decreased appetite, Dysarthria, Electroencephalogram abnormal, Encephalopathy, Enuresis, Fatigue, Grand mal convulsion, Headache, Intensive care, Lumbar puncture normal, Memory impairment, Nystagmus, Pyrexia, Somnolence, Tremor, Urinary incontinence, Weight decreased

Symptom Text: 60 second generalized tonic-clonic seizure followed by a second one 6 hours later; MRI negative; EEG markedly abnormal with frequent burst suppression activity; LP normal. No active infectious or neurological etiology found. Treating with antiepileptic and seeing slow recovery of mental status. 12/10 12/23 12/24 1/5/09: Hospital records received for dates of service 11/13/09 to 12/19/09: Dx: Encephalopathy, seizures, spinal lesion. Hospitalized after onset of tonic clonic seizures with bilateral upper and lower extremity shaking lasting 30 to 60 seconds with no respiratory compromise and urinary incontinence, unusual fatigue, fever, headache, sleeping more than normal. Hx. of enuresis worsened with admission, taking Dilantin and Trileptal. EEG abnormal but without epileptiform discharges. Also poor memory, poor appetite, ten pound weight loss over past month, nystagmus on lateral gaze both right and left, ataxic gait and slow, slurred speech. Intensive care unit admission after seizure with prolonged apnea. PICC Line placed. Treated with IVIG with marked improvement, though she did have a reaction to the IVIG with fevers, abdominal pain and a few days of low blood pressure. Discharged on antiepileptics.

Other Meds:

Lab Data: MRI - normal blood/CSF cultures - negative 12/10 12/23 12/24 1/5/09: Hospital records received for dates of service 11/13/09 to 12/19/09: Labs and diagnostics: Enterovirus PCR-Negative, CSF-no growth, MRI Brain-WNL. CT Spine-abnormal

History: Possible bipolar. 12/10 12/23 12/24 1/5/09: Hospital records received for dates of service 11/13/09 to 12/19/09: PMH: Wheezing, ADHD, Bladder infection, Allergy to amoxicillin, RAD.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **371572-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	05-May-2008		04-Dec-2009	07-Dec-2009	IL	WAES0806USA02864	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion missed, Drug exposure during pregnancy

Symptom Text: Information has been received from a specially trained medical technician for the Pregnancy Registry for GARDASIL vaccine, concerning a 26 year old female with diabetes and no drug reaction/allergies, who on 21-Jun-2007, 25-Aug-2007 and 28-May-2008 was vaccinated intramuscularly with 0.5 ml of first (lot# 660389/1968U), second (lot# 658100/0525U) and third (lot# 658556/1060U) doses, respectively, of GARDASIL vaccine and is pregnant. Concomitant therapy included NOVOLOG. On 07-Jun-2008 the patient took home pregnancy test that tested positive (LMP = 05-May-2008). Unspecified medical attention was sought, the patient was seen in office. No adverse event reported. At the time of this report the outcome is unknown. Follow-up information has been received from a person in the physician's office on 24-NOV-2009 who reported that on 21-JUL-2008 the patient had an ultrasound performed which identified a "missed AB", which was dated at 11 weeks gestation by LMP. The patient did "fine" after that, recovered. Upon internal review, "missed AB" was determined to be an other important medical event. This is one of two reports concerning the same patient (WAES#0911USA04901). A lot check has been initiated. No further information is available.

Other Meds: NOVOLOG

Lab Data: Ultrasound, 07/21/08, identified a "missed AB"; beta-human chorionic, 06/07/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 5/5/2008); Diabetes

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371574-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	12-Oct-2009	12-Oct-2009	0	04-Dec-2009	07-Dec-2009	FR	WAES0911USA04859	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ28290	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotension, Loss of consciousness

Symptom Text: Case received from Health Authorities on 23-NOV-2009 under the reference number N200911-448 and transmitted by SPMSD. Case received from the Health Authority, having a follow up in the narrative, even though the initial version was never received. A female patient received the third dose of GARDASIL (Lot number: NJ28290, Batch number NK30860) by intramuscular route on 12-OCT-2009. The patient had no adverse reaction history to vaccinations with GARADASIL. Adverse reaction history to other drugs was unknown. Few minutes after vaccination, the patient experienced severe hypotension with loss of consciousness. The adverse events evolved positively, without any drugs being used. At the time of reporting, the patient had recovered. Follow up received by the Health Authorities on 12-NOV-2009; upon contact with the reporter, the seriousness criteria was changed to serious. Other business partner numbers include E2009-10984. Hypotension and loss of consciousness was considered to be as other important medical event by the reporter. No further information expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371575-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		04-Dec-2009	07-Dec-2009	FR	WAES0912USA00001	07-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Non-Hodgkins lymphoma

Symptom Text: Information has been received from a specialist in hospital, concerning a female patient with no reported medical history who experienced non Hodgkin's lymphoma within an unspecified time frame after she had received a dose of GARDASIL (batch number not reported). The vaccination date and the number of dose received were not reported. The outcome was not reported. The physician considered Lymphoma (non-Hodgkin's) as other important medical event. Other business partner numbers include E200910994. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371619-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Feb-2009	25-Feb-2009	2	04-Dec-2009	07-Dec-2009	OH		20-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426F	1	Unknown	Unknown	HEP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Dry mouth, Fatigue, Feeling abnormal, Headache, Hypoacusis, Muscle contractions involuntary, Nausea, Paraesthesia, Syncope, Tunnel vision

Symptom Text: I am unsure of an accurate time, her new symptoms didnt start until after the second vaccine in the series of three. On 2/23/09 she was vaccinated and on 2/25 the symptoms started and have not gone away. Syncope several episodes, nausea, tunnel vision, muffled hearing, tingling limbs, dry mouth, burning sensations, overall "weird feeling/somethings not right" extreme fatigue, leg muscles contract or something and she cannot bend it until it stops. ```records received 12/29/2009. Clinic office visit rec. received for DOS 04/27/09. Rec (04/27/09) notes headaches on and off patch (no difference appreciated). Sexual activity. Given #3 gardasil. Record reflects HPV received 11/03/08, 02/23/09, 04/27/09. Hepatitis B given 05/13/2004 (rec. does not support provided report-of 4wks. of vac). Plan: restart patch. Ordered med: Ortho Eva. Disposition: return 6 months.

Other Meds:

Lab Data: EKG, ECG, MRI, CT Blood work, Seen by Neurologist who says her symptoms are not at all related to her Pineal Cyst, now they are asking we find a new doctor because she's 18, my thought is they don't know how to fix her so wash their hands o

History: pineal cyst 12/29/09 PMH: allergy-Relpax, arachnoid cyst, pineal gland dysfunction, congental anomalies of inner ear (2005), syncope (01/26/09), common migraine.

Prex Illness: no Time above is unknown, the system made me enter a time, the doctors office may have record of that

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371728-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	24-Nov-2009	24-Nov-2009	0	04-Dec-2009	07-Dec-2009	NM		23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oral pruritus, Pharyngeal oedema, Pruritus, Swelling

Symptom Text: Vaccine administered at 10 am at 10:30 patient returned and reported pruritis to face, tongue, swelling, throat felt thick. 50 mg Diphenhydramine IM at 10:38. Patient reported symptoms resolved.

Other Meds: MONONESSA

Lab Data: None

History: DMPA caused hives

Prex Illness: Chlamydia

Prex Vax Illns:

Vaers Id: **371754-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Nov-2009	18-Nov-2009	1	07-Dec-2009	07-Dec-2009	KS		08-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1157Y	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0216Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB359AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold compress therapy, Erythema, Injection site pain, Injection site swelling

Symptom Text: Redness, swelling and sorness at the vaccination site. Treatment included cool packs, Claratin 10mg in the morning and bendaryl 25-50mg at bedtime.

Other Meds: No other medicaitons

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371773-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Oct-2009	Unknown		07-Dec-2009	07-Dec-2009	CO		17-Jan-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1130X		Left arm	Unknown	
TDAP	SANOFI PASTEUR	C2768BA		Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0914Y		Left arm	Subcutaneously	
FLUN	MEDIMMUNE VACCINES, INC.	500687P		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event

Symptom Text: No adverse events to date. Patient was vaccinated with GARDASIL #1, LAIV, ADICEL, VARIVAX #2 on 10/7/09 after completing screening questionnaire that she is not pregnant. On 10/23/09 we were notified she is approximately 4 months pregnant. ```12/7/2009 OB-GYN records received, patient preganant, no side effects noted

Other Meds:

Lab Data: ```12/7/2009 OB-GYN records received Prenatal labs wnl

History: ```12/7/2009 OB-GYN records received PMH: None allergies: NKDA

Prex Illness: NONE ```12/7/2009 OB-GYN records received

Prex Vax Illns:

Vaers Id: **371854-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	30-May-2009		07-Dec-2009	08-Dec-2009	FR	WAES0912USA00169	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Ataxia, Demyelination, Dizziness, Hypoaesthesia, Steroid therapy

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on an unspecified date was vaccinated intramuscularly with a dose of GARDASIL. The physician reported that following vaccination with GARDASIL, on 30-MAY-2009, the patient experienced dizziness, ataxia and numbness. The patient was hospitalized and received 1gm of METHYLPREDNISONE IV for 3 days. On an unspecified date a magnetic imaging was performed on the brain that showed demyelinating plaques. On approximately 30-JUN-2009 the patient had recovered from the symptoms of dizziness, ataxia and numbness. The outcome for the demyelinating plaques was not reported. On approximately 30-JUN-2009 the patient had recovered from the symptoms of dizziness, ataxia and numbness. The outcome for the demyelinating plaques was not reported.. Additional information is not expected.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging on the brain showed demyelinating plaques

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **371855-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
33.0	F	21-Jan-2008	21-Jan-2008	0	07-Dec-2009	08-Dec-2009	FR	WAES0912USA00273	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Autoimmune disorder, Denervation atrophy, Muscle contractions involuntary, Myotonia, Neuromyopathy, Paraesthesia, Tachycardia

Symptom Text: Information has been received from a Health Authority (case no. 107184, local case no. IT547/09) concerning a 33 year old female who on 21-JAN-2008 was vaccinated with the first dose of GARDASIL (batch not reported) by intramuscular route. A second dose of GARDASIL was received on 19-MAR-2008. On 21-JAN-2008, the patient experienced asthenia, fasciculation, paresthesia, tachycardia and myotonia. The diagnosis of an autoimmune disorder was reported as Isaacs syndrome and acquired neuromyotonia. The patient was treated with immunotherapy as cortisone, ENDOXAN and IGVENA with poor response. In March 2009, the patient had antivoltage gated potassium channel antibodies positive. On 23-APR-2009, electromyography was abnormal with denervation and myotonic potential. Outcome is not reported. Other business partner numbers include E2009-10955. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: electromyography, 23Apr09, abnormal with denervation an myotonic potential; laboratory test, ??Mar09, VGKC-Abs, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **371856-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	23-Nov-2009		07-Dec-2009	08-Dec-2009	FR	WAES0912USA00294	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1883U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Apnoea, Immediate post-injection reaction, Joint stiffness, Loss of consciousness, Malaise, Musculoskeletal stiffness, Nausea

Symptom Text: Information has been received on 24-NOV-2009 from a healthcare professional concerning a 15 year old and one month female patient who on 23-NOV-2009 received the first dose of GARDASIL (lot # 1883U and batch number NH50490) via intramuscular route in the left deltoid. Immediately after vaccination and during ten seconds; the patient experienced malaise with loss of consciousness, limbs stiffness, apnea and jaw stiffness. Afterwards, she recovered from loss of consciousness without loss of memory but complained of nausea. Neither tonico-tonic attack nor cutaneous eruption were observed. The outcome was not reported for nausea and for jawbone stiffness. The outcome for malaise was recovered. Upon internal review, apnea was considered to be an other important medical event. Other business partner numbers include E2009-10811. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371857-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	01-Nov-2009		07-Dec-2009	08-Dec-2009	FR	WAES0911CZE00001	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a 25 year old female who in December 2008, February 2009 and July 2009 was vaccinated with 3 doses GARDASIL. In November 2009, the patient experienced cervical high grade intraepithelial lesion (C1N3). Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **371858-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Sep-2008	01-Jan-2009	122	07-Dec-2009	08-Dec-2009	FR	WAES0911USA04860	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune thyroiditis, Hypothyroidism

Symptom Text: This case was received from gynecologist on 25-NOV-2009. According to one of the reporter's patient, her/his sister (age not reported) developed Hashimoto's hypothyroidism within an unspecified timeframe after she was vaccinated with a dose of GARDASIL (dose, route, lot number and batch number not reported) on an unspecified date. The patient's medical history, family history and the outcome were unknown. Additional information was received on 01-DEC-2009. The patient's date of birth was provided: the female patient was 18 years old at the time of the reaction. She had received the first dose of GARDASIL in January 2007, the second dose in September 2008 and the third dose in June 2009. Hypothyroidism was diagnosed in January 2009. The reporter had no further information at the time of reporting. Upon internal review Hashimoto's thyroiditis was determined to be an other important medical event. Other business partner numbers included: E2009-10970, Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 371859-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	05-Jan-2009	05-Aug-2009	212	07-Dec-2009	08-Dec-2009	FR	WAES0912USA00332	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0747X	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Gastrointestinal disorder, Myelitis transverse, Neurological symptom, Nuclear magnetic resonance imaging abnormal, Paraplegia

Symptom Text: Information has been received from Health Authority, (H.A. reference #: DK-DKMA-20093924), concerning a 12 year old females patient (weight: 55kg, height: 169 cm) with no concurrent disease who was vaccinated IM with the third dose of GARDASIL (lot number: 0747X, batch number NJ38950, site of administration not reported) on 13 JUL-2009. On 05-AUG-2009, the patient developed myelitis transverse and subsequently and subsequently incomplete paraplegia at neurological level Th9. The patient was admitted to hospital (date and duration not reported). The score according to ASIA impairment scale was AIS-B. The patient's bladder and colon were affected, in addition to muscle function and sensibility (not further specified). MR scan column throacalis was performed on 05-AUG-2009 and 11-AUG-2009. It was reported that the result of the MR scan revealed signal changes on medulla and on conua medullaris that were consistent with myelitis transverse. Signal fluid was examined for Herpes Simples virus type 1 and 2, varicella zoster virus, enterovirus, Hycoplasma pneumoniae and adenovirus. Spinal fluid was negative for all tests, except Mycoplasma pneumonaie IgG. Faeces were negative for enterovirus. A swab of tonsillis was negative for Mycoplasma pneumoniae. Aquaporin antibody test, Ana Hep-2-screening, gliadin antibody IgA and IgG tests, tissue glutaminase antibody test, Chlamydia test, GQlb gangliosid antibody test were all negative. The patient had not concurrent disease. The patient was vaccinated with the first and second dose of GARDASIL (lot number, batch number and site of administration not reported) on 15-Jan-2009 and 12-Mar-2009, respectively. No adverse reaction was reported. It was reported that the patient had not recovered. Other business partner number is included E2009-10977. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 05Aug09, Columna thoracalis, see narrative; magnetic resonance imaging, 11Aug09, Columna thoracalis, see narrative; spinal tap, For enterovirus: negative; diagnostic laboratory test, Aquaporin 4 antibody test:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **371860-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Feb-2009	01-Sep-2009	210	07-Dec-2009	08-Dec-2009	FR	WAES0912USA00323	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1316U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eosinophilia, Eosinophilic cellulitis, No reaction on previous exposure to drug, Urticaria

Symptom Text: Information has been received from a dermatologist concerning an 18 year old female patient who on 03-FEB-2009 was vaccinated with the first dose of GARDASIL (Lot # 1316U) (Batch # NH45640), on 16-APR-2009 was vaccinated with the second dose of GARDASIL (Lot# 1316U) (Batch # NH45640) which were well tolerated. On 24-AUG-2009 the patient was vaccinated intramuscularly into the deltoid muscle with the third dose of GARDASIL (Lot # 1695U) (Batch # NH25730). It was reported that in the beginning or middle of September 2009 the patient experienced eosinophile infiltration's and wheals at the whole integument. The patient presented to the dermatologic outpatient department of a hospital: Laboratory test showed increased eosinophile granulocytes. Diagnosis of WELL'S syndrome was established. At the time of reporting the symptoms were still ongoing. Upon internal review the case was considered medically significant. Other business partner numbers include E2009-10815. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, increased eosinophile granulocytes; diagnostic laboratory test, diagnosis os WELL'S syndrome

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **371934-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Oct-2009	22-Oct-2009	0	07-Dec-2009	08-Dec-2009	MA		17-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Reflux oesophagitis, Vomiting

Symptom Text: Received 2nd GARDASIL 1-3-08 & vomited every day or every other day for 6 months - saw GI with no finding - received 3rd on - 10-22-09 & started to vomit again. ```12/10/09 Pediatric records received for DOS 03/03/08, 11/06/08, 12/22/08 Pt. presents with nausea and vomiting X 3-4 weeks. Starts at school with nausea, then vomits at home Diagnosis: Chronic reflux esophagitis

Other Meds:

Lab Data:

History: None ```12/10/09 PMH: NKDA; IBS; sinusitis

Prex Illness: None

Prex Vax Illns:

Vaers Id: **372072-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Dec-2009	03-Dec-2009	0	08-Dec-2009	08-Dec-2009	NY		09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3356AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Hyperhidrosis, Pallor

Symptom Text: Patient given above injection in left deltoid, then GARDASIL in right deltoid, was talking to nurse while sitting on exam table. (Approx 3 min after vaccine given). Patient fell back against wall, then flapped to side on exam table. Nurse moved forward, swung legs onto table and placed on side. Noted pallar, diaphoresis. Responsive after 30 sec. Placed supine, feet elevated, given iced tea recovered well over few minutes.

Other Meds: Loestrin

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372103-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Dec-2009	04-Dec-2009	0	08-Dec-2009	08-Dec-2009	VA		08-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500834P	0	Unknown	Unknown	
FLU	SANOFI PASTEUR	U3376AA	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0669Y	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3096AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient had a syncopal episode less than 3 minutes after recieving injection. Eased pt down to the floor. Fanned patient off and gave her soda to drink. Took patient to room to lay down for 15 minutes. BP 98/58. Patient voiced no signs or symptoms of any further abnormal/adverse reaction 15 minutes after Gardasil injection.

Other Meds:

Lab Data: Blood pressure shortly after the time of the event was 98/58.

History: Anxiety

Prex Illness: None

Prex Vax Illns:

Vaers Id: **372118-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	04-Dec-2009	05-Dec-2009	1	08-Dec-2009	08-Dec-2009	OK		10-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0880Y	1	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1497X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: PATIENT HAS A RAISED RED SPOT AT THE INJECTION SITE. THE SITE IS WARM TO TOUCH AND SORE. BENADRYL GIVEN ON 12/05/2009, AND CORTISONE CREAM APPLIED TO THE AFFECTED AREA.

Other Meds: PATIENT TAKES CONCERTA 36MG, DDAVP, ENABLEX, ZYRTEC, AND NITROFUR DAILY.

Lab Data:

History: HAS HISTORY OF ACUTE LYMPHOBLASTIC LEUKEMIA, GENERALIZED SEIZURE DISORDER, AND ADHD.

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **372135-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		08-Dec-2009	09-Dec-2009	--	WAES0911USA02052	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning "several patients" who were vaccinated with GARDASIL. The nurse reported that after receiving GARDASIL the patient fainted. The patients sought unspecified medical attention. Follow-up information has been received from the nurse practitioner. One patient (age and gender not reported) had a known seizure disorder. The nurse practitioner could not confirm that these events were definitely related to vaccination with GARDASIL. The practice began observing the patient for 15 minutes after the patient received vaccination as a result of the event. Upon internal review, seizure disorder was determined to be an other important medical event. This is one of three reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 372138-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Dec-2007	01-Dec-2007	0	08-Dec-2009	09-Dec-2009	FR	WAES0912USA00331	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Appendicectomy, Appendicitis, Blood test normal, Colonoscopy normal, Constipation, Diarrhoea, Endoscopy upper gastrointestinal tract, Food allergy, Frequent bowel movements, Headache, Histamine intolerance, Hordeolum, Lactose intolerance, Lip dry, Muscle spasms, Nasal congestion, Nausea, Oropharyngeal blistering, Parosmia, Stool analysis abnormal, Vomiting

Symptom Text: Information has been received from a gynaecologist concerning a 15 year old female patient who in December 2007 was vaccinated with the third dose of GARDASIL (lot#, injection route and site not reported). The gynaecologist provided a summary created by the patient in which she described the course of her medical report. Following the vaccination she complained of abdominal pain and cramps with increased frequency. In August 2008, the patient experienced appendicitis. In September 2008, the patient developed diarrhoea, obstipation, stye, dry lips, swollen nasal mucosa, headache, nausea, vomiting, sensitivity to smells and blistering of mouth. In the end of October 2008, the patient had an appendectomy but symptoms persisted. A colonoscopy and gastroscopy were carried out on unspecified dates and showed no pathological findings. Also blood analysis (no further specified) showed normal results. In March 2009, a blood and stool sample were taken and showed allergy to several foods and a lactose and histamine intolerance. After corresponding diet, symptoms improved. The final outcome was not reported. The physician stated that the mother of the patient considered a causal relation between vaccination and the symptoms. Other business partner number included: E200911051. Case closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **372139-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Oct-2009	30-Oct-2009	21	08-Dec-2009	09-Dec-2009	FR	WAES0912USA00358	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ22910		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Fatigue, Headache, Nausea, Tremor

Symptom Text: Information has been received from SPMSD as part of a business agreement. Initial case reported on 30-NOV-2009 by the mother of the patient to SPMSD. Additional information was received from HCP on 01-DEC-2009. Case was considered serious due to other medically important condition (seizure). It was reported that a 13-year old girl was vaccinated with GARDASIL (MSD, first dose, batch number NJ33910, route not reported) on 09-OCT-2009. Three weeks after vaccination, on 30-OCT-2009, the girl experienced a seizure with convulsions, shaking, headache, dizziness and nausea. The attack lasted for one hour. According to the mother, the girl was never unconscious nor did she experience any convulsions, but according to the medical record, the patient did experience convulsions during the seizure. At the time of the event, the patient was visiting with a friend's family. The girl went to the hospital where she was treated with sedatives (mfr unknown) and headache tablet (mfr unknown). Blood and urine samples (no details reported) taken on 30-OCT-2009 could show no finding. Afterwards she was tired, but then ok. The girl has no memory from the actual seizure. Some days later, on 04-NOV-2009, the girl experienced the same seizure once again, same symptoms, this time during school hours. The school phoned her father, who came and saw the daughter in convulsions. The girl went to the emergency room in an ambulance. Blood tests (no details reported) taken on 04-NOV-2009 showed no finding. An MR taken on 06-NOV-2009, found nothing un-normal. Today the girl is feeling ok, but is under investigation for epilepsy. The outcome is recovered. Case is closed. This was originally reported by a health care professional. Other business partner numbers include E2009-11039.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 30 Oct 09, blood and urine test normal; diagnostic laboratory test, 04 Nov 09, blood test normal; magnetic resonance imaging, 04 Nov 09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 372140-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	20-Nov-2008	21-Dec-2008	31	08-Dec-2009	09-Dec-2009	FR	WAES0912USA00362	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Clonus, Laboratory test normal, Nuclear magnetic resonance imaging brain normal, Partial seizures, Pyrexia, Vaccine positive rechallenge, Virus serology test negative

Symptom Text: Information has been received from a Health Authority (case no. 107477, local case n. IT561/09) concerning a 20 year old female who on 20-NOV-2008 the patient was vaccinated with the third dose of GARDASIL (batch number not reported). On 21-DEC-2008 the patient presented with high fever and clonus to the fingers of the right hand. It was also reported that the patient was vaccinated the first dose of GARDASIL on 02-MAY-2008 following which on 12-JUN-2008 she experienced clonus of the head towards the right side and on 03-JUL-2008 a feeling of the face pulling to the right and aphasia with loss of consciousness. The second dose of GARDASIL vaccine was administered on 17-JUL-2008 and the patient experienced a similar reaction. The patient was hospitalized, routine labwork within normal limits; cerebrospinal (CSP) exam with serology for neurotropic viruses was negative; magnetic resonance imaging (MRI) brain negative; electroencephalography (EEG) showed continuous partial epilepsy. She was treated with KEPPRA. The reported outcome is not recovered. The case is closed. Other business partner number included E2009-11086.

Other Meds: Unknown

Lab Data: Physical examination, ??08, within normal limits; Magnetic resonance imaging, ??08, negative; Electroencephalography, ??08, continuous partial epilepsy; Cerebrospinal fluid culture, ??08, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **372143-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Dec-2009	09-Dec-2009	--	WAES0912USA00447	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Idiopathic thrombocytopenic purpura

Symptom Text: Information has been received from a physician's assistant concerning her friend's daughter who on an unknown date was vaccinated with the first dose of GARDASIL (lot # not given). On an unspecified date, after receiving GARDASIL, the patient experienced idiopathic thrombocytopenic purpura "ITP". Subsequently, on an unknown date, the patient recovered. The patient sought unspecified medical attention. It was reported that the patient will not receive further doses of GARDASIL. Upon internal review idiopathic thrombocytopenic purpura "ITP" was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **372145-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Nov-2009	23-Nov-2009	0	08-Dec-2009	09-Dec-2009	CA	WAES0912USA00455	27-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 23-NOV-2009 was vaccinated with a second 0.5 ml dose of GARDASIL (route, site and lot # not reported). Concomitant vaccine included a dose of MENACTRA and a dose of H1N1 on the same day (23-NOV-2009). The physician reported that the patient experienced fainting and seizure for 15 seconds after getting the second dose of GARDASIL on 23-NOV-2009. At the time of the report the outcome of the patient was recovered on an unspecified date. The patient sought unspecified medical attention. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **372146-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	30-May-2009		08-Dec-2009	09-Dec-2009	FR	WAES0912USA00459	09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Ataxia, Demyelination, Dizziness, Hypoaesthesia, Steroid therapy

Symptom Text: Information has been received from a physician concerning a 17 year old female who was vaccinated with a dose of GARDASIL IM on an unspecified date. On 30-MAY-2009 the patient experienced dizziness, ataxia and numbness. She was hospitalized and received 1 gm METHYLPREDNISONE IV for 3 days. The MRI on the brain showed demyelinating placks. She recovered from the symptoms after 1 month on 05-JUL-2009. No further information is available.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging demyelinating placks

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372172-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Sep-2008	23-Sep-2009	365	08-Dec-2009	09-Dec-2009	CA		09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426F	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: Pt. had dizziness, then LOC x 1-2 inches after GARDASIL. Pt. recovered after the provider's help.

Other Meds:

Lab Data:

History: Asthma

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372221-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		08-Dec-2009	09-Dec-2009	WA		09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Seizure activity for approx 5-10 secs about 2 mins after injection.

Other Meds:

Lab Data: None

History: Asthma; Graves disease

Prex Illness: None

Prex Vax Illns:

Vaers Id: **372259-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	03-Nov-2006	17-Jan-2007	75	07-Dec-2009	09-Dec-2009	--		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0689F	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Antiphospholipid syndrome, Asthenia, Autoimmune disorder, Bronchospasm, Dizziness, Dyspnoea, Headache, Heart rate increased, Hyperventilation, Hypoglycaemia, Malaise, Oxygen saturation decreased, Pallor, Palpitations, Presyncope, Pulmonary embolism, Syncope, Thrombosis, Vertigo, Vision blurred, Wheezing

Symptom Text: My daughter was a freshman (2006) in college when she fainted outside in the snow on campus in the month of January. She was taken to the student health center, then the hospital and released. She was mistakenly diagnosed with anxiety. The college nurse contacted me and insisted that something else was very wrong because my daughter's oxygen level was below normal. Upon the nurse's urging, I took my daughter to a pulmonologist. She was given a chest scan. I was told to admit her to the hospital immediately due to multiple pulmonary embolisms in her lungs. She was hospitalized for 5-7 days. She was then under the care of a hematologist who diagnosed her with an auto-immune disorder called anti-phospholipid antibody syndrome. Neither side of the family has any type of auto-immune disorder. Three years later she continues to take a blood thinner. We do not know how long she was functioning with the clots in her lungs before the fainting incident. I believe that the college nurse saved her life. This past August on the news, it was mentioned that GARDASIL has been found to cause fainting, clotting and auto immune disorders. I was suspicious that the vaccine caused this disorder in my daughter so when I heard the news report, my fears were confirmed. This clotting diagnosis occurred within 6 months of the time frame that she had the 2 of 3 recommended series of this vaccine. (The first dosage was in August. The second dosage was given in November). The manufacturer of this vaccine continues to aggressively market this product despite the problems associated with it. ```records received 12/10/09. Immunization rec. for DOS 11/03/06. Rec. reflects no illness on date of immunization. ```records received 12/10/09. Student health clinic rec. for DOS 01/17/07-04/19/07. Assessment: Near syncope/bronchospasm, hypoglycemia. vertigo. Clinic note of 01/17/07: Patient c/o SOB, feeling weak. Patient pale. Pulse ox. 88-91%. Plan-transport for Ed. evaluation. Clinic note 01/22/07: c/o difficulty breathing, rapid heart rate.

Other Meds:

Lab Data: Hematologist has tests indicating auto-immune disorder. Pulmonologist has report indicating pulmonary embolism. 12/10/09 Diagnostic tests: Pulse OX-88-91%. 12/15/09 Diagnostic tests: CT scan chest- mult. large pulmonary emboli in central

History: None 12/10/09 PMH: NKDA ```records received 12/18/09. Clinic coagulation records received for DOS 03/22/07-08/16/07. 12/18/09 PMH: Palpitations (3-4 years ago).

Prex Illness: none

Prex Vax Illns:

Vaers Id: **372260-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Dec-2009	08-Dec-2009	0	08-Dec-2009	09-Dec-2009	PR		09-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	NULL	0	Unknown	Intramuscular	
	VARCEL	UNKNOWN MANUFACTURER	NULL	1	Unknown	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Dizziness, Muscle rigidity

Symptom Text: Mareo, rigidez muscular, desmayo, debilidad corporal.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: ~HPV (Gardasil)~1~0.00~

Vaers Id: **372346-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Apr-2009	Unknown		09-Dec-2009	10-Dec-2009	MD	WAES0912USA00467	10-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female patient who in April 2009 was vaccinated with GARDASIL (dose unspecified). The reporter mentioned that after vaccination the patient experienced seizures. The physician stated that the patient received the dose of GARDASIL and then sometime after called the office and wanted to know if there were any correlations between getting GARDASIL vaccine and having seizures. The physician did not believe that there was any correlation but he is not sure. The patient sought unspecified medical attention. The patient's outcome was not reported. Upon internal review, seizure was considered an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372348-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Nov-2009	18-Nov-2009	0	09-Dec-2009	09-Dec-2009	MI		10-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3355AA	7	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1164Y	1	Left arm	Subcutaneously	
	HEPA	MERCK & CO. INC.	0912Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3044AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0969Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Pain, Vomiting

Symptom Text: Parent called and verbalized child c/o headache day of vaccines,body ache,headache, nausea and vomiting three days after vaccines.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372450-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	08-Dec-2009	08-Dec-2009	0	09-Dec-2009	10-Dec-2009	WA		10-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Cough, Dyspnoea, Myalgia, Pain, Pyrexia

Symptom Text: dry cough, body aches, difficulty breathing, joint pain, muscle pain, fever

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **372482-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Dec-2009	01-Dec-2009	0	10-Dec-2009	11-Dec-2009	CA	WAES0912USA00671	11-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Convulsion, Dizziness, Headache, Neck pain, Tonic clonic movements

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who started GARDASIL on an unknown date. The patient has no relevant medical history, and past drug includes no prior reactions to GARDASIL. On 01-DEC-2009 the patient was vaccinated with her third dose of GARDASIL (lot # 661703/0651X) in the right deltoid. Concomitant therapy included hormonal contraceptives (unspecified). After getting this injection, the patient reported feeling faint to the nurse who was still in the room, the nurse observed the patient to have tonic-clonic movements. The patient's blood pressure and pulse were monitored and reported to be normal, she was observed by the physician to be doing well and he felt that she was okay to go home. On 02-DEC-2009 a follow-up phone call was made to the physician's office stating that the patient had a severe headache, back ache and neck pain. He did not get to speak directly to the patient or her mother. Upon internal review, seizure/convulsion was determined to be an other important medical event. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: blood pressure, 12/01/09, Monitoring of blood pressure and pulse was normal

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372485-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Nov-2009	24-Nov-2009	0	10-Dec-2009	10-Dec-2009	PA		10-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	1397Y	0	Right leg	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049CA	0	Right leg	Intramuscular	
HPV4	MERCK & CO. INC.	1013Y	0	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Oropharyngeal pain, Pain in jaw, Visual impairment

Symptom Text: Visual disturbance x3 min. After vaccines per mother- also sore throat & jaw pain (resolved in one day) was seen in office day after immunizations. No stridor, no audible wheezing. + chest tight. ? reaction to vaccinations - vs. h/o bronchospasms - ordered Albuterol HFA. 2 puffs q6-8 x 1 wk.

Other Meds: SEROQUEL

Lab Data:

History: Bipolar

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372516-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	10-Dec-2009	10-Dec-2009	0	10-Dec-2009	10-Dec-2009	FL		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y		Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	97845P2		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dry skin, Injection site erythema, Injection site oedema, Rash papular, Skin discolouration, Skin warm

Symptom Text: Client reported redness onto LDT with numerous 3-4 raised areas measuring totaling 40 mm-60 mm. No open areas noted. No itching presented. Vital Signs: 9:25 AM-107/70;75,20-no c/o SOB. No c/o laryngospasm. A/O x3. Skin color-pink/skin-warm & dry. ARNP informed with recommendation of Benadryl IM; Dept Director/Dr. called at 10 AM with continued complaints of local reaction on LDT with Telephone Order for Benadryl 25 mg IM STAT-given to RDT. Tolerated well with good effect. Vital Signs: @ 10:30 AM- 115/75; 84, 20- No SOB, No laryngospasm, Skin Color-pink; skin warm/dry. 11 AM: Noted marked decrease edema and redness at injection site with area. No open areas noted. 11:30 AM Injection site noted with slight pink colored with no redness noted. Vital Signs-115/71; 88, 20. No SOB, No laryngospasm noted. Color-pink/skin-warm/dry. Emergency teaching provided to call EMS/911 for SOB or Emergency TX is required. Client able to repeat with good understanding.

Other Meds: BENDARYL 25 MG IM STAT RDT

Lab Data:

History: Client reported previous lactose intolerance with NKDA

Prex Illness: Client denies

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372561-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Nov-2009	17-Nov-2009	1	10-Dec-2009	10-Dec-2009	OH		23-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	3	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Back pain, Impaired work ability, Joint range of motion decreased

Symptom Text: Back pain and bilateral side pain. No numbeness, loss of continence, weakness. Complains of limited range of motion..difficulty performing activities of daily living without assistance. ```12/15/09 PCP records received for DOS 11/16/09, 12/10/09. Pt. presented on 12/10/09 with bliateral trunk pain radiating to thighs. Tripped by friend 1 week ago and fell flat onto back. Symptoms are worsening; states difficulty with ADLs. Neurology referral, ortho referral given. Treated with Ibuprofen. Assessment: back pain

Other Meds:

Lab Data: X-ray of lumbar spine - results pending ```12/15/09 Diagnostics: Lumbar spine Xray: bilateral defects of L4 pars interarticularis

History: Asthma ```12/15/09 PMH: NKDA; asthma

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372573-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		10-Dec-2009	11-Dec-2009	FR	WAES0912MEX00003	11-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female who in approximately 2009 was vaccinated with GARDASIL specific dose number and date not reported. In 2009 the patient experienced convulsion details was not provided. After several attempts no additional information was obtained. By internal review the convulsion was considered as other medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372639-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Dec-2009	09-Dec-2009	1	10-Dec-2009	11-Dec-2009	MD		11-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087	2	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1070Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Swelling

Symptom Text: 1 inch in diameter reddened and swollen

Other Meds:

Lab Data:

History: none

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372747-1** **Related reports:** 372747-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Dec-2009	03-Dec-2009	2	11-Dec-2009	11-Dec-2009	KY		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Urticarial rash - treated with steroids, antihistamine vaccinated at health dept - presented here 3 days later with diffuse urticarial rash. This was her second dose of GARDISIL.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372747-2** **Related reports:** 372747-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Dec-2009	03-Dec-2009	2	21-Dec-2009	22-Dec-2009	KY		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Steroid therapy, Urticaria

Symptom Text: Urticarial rash-treated with steroids, antihistamine. Vaccinated at health dept.-presented here 3 days later with diffuse urticarial rash. This was her second dose of GARDASIL.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372812-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	19-May-2008	01-Mar-2009	286	11-Dec-2009	14-Dec-2009	--	WAES0807USA02901	14-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood test, Caesarean section, Drug exposure during pregnancy, Labour complication

Symptom Text: Information has been received from a nurse practitioner and a 26 year old female consumer for the Pregnancy Registry for GARDASIL concerning herself who on 19-MAY-2008 was vaccinated intramuscularly in the deltoid with her first dose of GARDASIL (lot# not reported) and became pregnant. There was no concomitant medication. The patient's LMP was 19-MAY-2008 and EDD was 23-FEB-2009. Subsequently the patient experienced no adverse symptoms. The patient sought medical attention with an office visit on an unspecified date. The patient had blood work and a urine pregnancy test to confirm the pregnancy. The patient's outcome was not reported. Follow-up information was received from the consumer who stated that she had a baby boy who is now nine months old; healthy and normal with no problems. She also said her pregnancy was "very good", and she was one week overdue when she went into labor. Additionally she reported an "emergency" cesarean section during labor because the baby "wasn't coming down" and had the umbilical cord wrapped around his arm and after a while" he couldn't take it any more". The reporter stated the baby was fine after he was born and she recovered very well from the surgery. Upon internal review, umbilical cord abnormality was considered an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: diagnostic laboratory; urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 5/19/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372817-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-Nov-2009	23-Nov-2009	0	11-Dec-2009	14-Dec-2009	TX	WAES0912USA00453	14-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia oral, Swollen tongue, Vaccination complication, Vision blurred

Symptom Text: Information has been received from a certified medical assistant concerning a 21 year old female with asthma and no known drug allergies who on 23-Nov-2009 was vaccinated intramuscularly with her second 0.5ml dose of GARDASIL (lot number 661046/0381X). On 23-NOV-2009, after receiving the vaccine, the patient experienced tongue swelling numbness and blurred vision. Subsequently, the patient recovered from tongue swelling numbness, tongue swelling numbness and blurred vision on the same date. The patient sought medical attention by making a phone call and by contacting the emergency squad. Follow up information was received from a certified medical assistant concerning the 21 year old female. She reported that the patient received GARDASIL vaccination on the following dates: dose # 1 was given on 10-AUG-2009, lot number 661046/0381X and dose # 2 was given on 23-NOV-2009 at 1:45p.m., lot number 661046/0381X (into the left deltoid). The patient did not receive any concomitant vaccinations when the GARDASIL vaccinations were administered. The C.M.A stated that the patient had the reaction to the second dose of GARDASIL when she went back to school. The patient was complaining of tongue swelling, numbness and blurred vision. The patient was a student at the University. The patient called the physician's office and was advised to go to the nearest Emergency Room. An Ambulance was called to take the patient to the Hospital and stabilized the patient. The patient was treated for her reaction to the GARDASIL vaccination (treatment unknown to the reporter). The patient did not go to the Hospital. The patient recovered on 23-NOV-2009. The patient stated that she would not receive the third dose of GARDASIL. The C.M.A. stated that she called the patient to inquire how she was doing and the patient did not return the phone call. The patient did say she received a shot but was not sure. The reporter considered that tongue swelling, numbness and vision blurred required intervention to prevent serious criteria. Additional informa

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **372892-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Aug-2009	07-Aug-2009	0	11-Dec-2009	14-Dec-2009	FR	B0610546A	14-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ00020	0	Unknown	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	XHBUB444E1		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bronchospasm

Symptom Text: This case was reported by a regulatory authority (# ES-AGEMED-908985234) and described the occurrence of bronchospasm in a 13-year-old female subject who was vaccinated with (ENGERIX B, GlaxoSmithKline), (non-gsk) (GARDASIL). On 7 August 2009 the subject received unspecified dose of ENGERIX B (intramuscular), 1st dose of GARDASIL (intramuscular). On 7 August 2009, less than one day after vaccination with ENGERIX B and GARDASIL, the subject experienced bronchospasm. The regulatory authority reported that the event was clinically significant (or requiring intervention). On 7 August 2009, the event was resolved. The regulatory authority reported that the event was possibly related to vaccination with ENGERIX B and GARDASIL.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372910-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Mar-2009	22-Sep-2009	189	11-Dec-2009	14-Dec-2009	FR	WAES0912USA00953	14-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1283U	2	Unknown	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Sudden death

Symptom Text: Information has been received from the agency via Case Line listing via CSL, as part of a business agreement, concerning an 18 year old female patient with disseminated herpes viral disease who on 17-MAR-2009 was vaccinated with the third dose of GARDASIL (batch #NJ11440, lot# 1283U). The second suspect therapy included DEPO-PROVERA which was administered IM, 600 mg yearly, from 2007 October to 2009 January. On 22-SEP-2009 the patient developed sudden death (severe). It was unknown if the patient sought medical attention. A lot check has been initiated. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Herpes virus infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372917-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Dec-2009	12-Dec-2009	0	11-Dec-2009	14-Dec-2009	PA		14-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2906AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0315Y	0	Right arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP013AA	0	Left arm	Intramuscular	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	98446P1A	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3098AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Loss of consciousness, Muscle spasticity

Symptom Text: 30 second episode, child lost consciousness while sitting hit her head against piece of furniture episode of espasticity might have had tonic-clonic episode test arm recovery completely with 30 seconds.

Other Meds: DIMETAPP Am 12/11/09 1 tablespoon

Lab Data: Possible isolated seizure episode

History: None

Prex Illness: None/pharyngitis

Prex Vax Illns:

Vaers Id: **372938-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Apr-2008	06-Oct-2009	547	11-Dec-2009	14-Dec-2009	PA		02-Feb-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1448U	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2370AA	0	Left arm	Intramuscular	
HEPA	UNKNOWN MANUFACTURER	AHAVB233AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Complex regional pain syndrome, Cyanosis, Disturbance in attention, Fatigue, Feeling cold, Insomnia, Joint dislocation, Joint swelling, Migraine, Myalgia, Oedema peripheral, Oropharyngeal pain, Pain, Palpitations, Physiotherapy, Pyrexia, Tremor, Vision blurred, Wheelchair user

Symptom Text: After the first shot, Her eyes stopped focusing and she got migraines. After the second shot, which she recieved on 8/3/09 Her ankles started to swell and be very painful. Her legs turn blue. Her knees, ankles, hips, elbows, and shoulders fall out of place. Her hands, feet, and legs also swell. She is constantly cold. her hands and her head shake uncontrollably. She has heart palpatations. She cant sleep.At times it is to painful to get out of bed. She has trouble concentrating. She has been to the er, then doctor, then the er again, then the rheumatologist, the er again, and the childrens institute where she may have to stay for two or more weeks for intense physical therapy, although to week at this time. She has to be built up before she can begin. ```12/15/09 ED records received for DOS 10/06/09. Pt. presents with bilateral painful joints in upper and lower extremities Discharged home to f/u with rheumatology. ```12/16/09 Physical therapy records received for DOS 12/01/09 DX: Reflex Neurovascular Dystrophy. ```12/17/09 Rheumatology records received for DOS 10/27/09, 10/30/09 Pt. initially presented on 10/13/09 with arthralgias and myalgias of three months duration. Has experienced increasing fatigue, and pain in the knees, ankles and hips; swelling of feet and fingers; fever and sore throat; has been using wheelchair to move around. DX: arthralgias and myalgias

Other Meds:

Lab Data: They tested for lymes disease, cancer, lupus, etc. All tests come back negative so they told us she hs reflex neurovascular dystrophy but weare not sure that the diagnosis fits. ```12/15/09 Labs: ANA: negative; lyme screen: negative. ```1

History: She had a goider on her thyroid. ```12/17/09 PMH: hypothyroidism, depression, benadryl allergy; Hashimoto's thyroiditis

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372952-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	10-Dec-2009	10-Dec-2009	0	12-Dec-2009	14-Dec-2009	OH		14-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Pain in extremity

Symptom Text: I am having and have been having serious pain in my arm and hand and wrist since the night after I recieved the vaccine.

Other Meds: Meridia. Prilosec.

Lab Data:

History: None.

Prex Illness: No.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **372970-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	11-Jan-2007	17-Nov-2009	1041	13-Dec-2009	14-Dec-2009	FR		14-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Gaze palsy, Hypoaesthesia, Paralysis, Relapsing-remitting multiple sclerosis, Speech disorder

Symptom Text: I awoke with palsy on my right arm, right side of face, numbness in right leg and difficulty talking and keeping my gaze. Has since been diagnosed with relapsing-remitting MS - NIL symptoms of this before my Gardasil vaccine.

Other Meds:

Lab Data: Positive for MS in Blood Test, MRI, subsequent MRI scans and 2 x Lumbar Punctures.

History: Hypo-thyroid congential - however treated.

Prex Illness: NIL

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **373031-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Dec-2009	09-Dec-2009	0	14-Dec-2009	14-Dec-2009	FL		14-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB357CA	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	1013Y	0	Right arm	Unknown	
TDAP	SANOFI PASTEUR	C3250AA	0	Left arm	Unknown	
VARCEL	GLAXOSMITHKLINE BIOLOGICALS	08494	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Patient with urticaria since late last night. S/p immunizations.

Other Meds: None

Lab Data:

History: Nonsignificant

Prex Illness: None (well child)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **373079-1** **Related reports:** 373079-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Nov-2009	24-Nov-2009	0	14-Dec-2009	14-Dec-2009	VA		14-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	J00840P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0312Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness

Symptom Text: Received HPV and H1N1 vaccine. RN accompanied client to bill pay and told to wait 15 min before leaving. Client fell while waiting at bill pay and hit back of head on floor. Unresponsive approx 30 sec BP 118/78, P64, R16. Waited at HD about 40 min - ER with friend. No Rx at ER.

Other Meds: None

Lab Data: none

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **373079-2** **Related reports:** 373079-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Nov-2009	24-Nov-2009	0	14-Dec-2009	14-Dec-2009	VA	VA09033	17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500840P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Immediate post-injection reaction, Unresponsive to stimuli

Symptom Text: Client received HPV & H1N1 vaccines. RN accompanied client to bill pay & told to wait 15 min. before leaving. Client fell while waiting at bill pay & hit back of head on floor. Unresponsive approximately 30 sec. BT 118/78; P 64; R 16. Waited at HD about 40 min - to ER with a friend. No Rx at ER.

Other Meds: none

Lab Data: None

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **373086-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.3	M	23-Jan-2009	23-Jan-2009	0	14-Dec-2009	15-Dec-2009	MI	WAES0903USA01999B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Intensive care, Respiratory distress

Symptom Text: Information has been received concerning a male baby who on 23-JAN-2009, during gestation, was exposed to GARDASIL. The baby was also exposed to vitamins (unspecified) and influenza virus vaccine (unspecified). The baby was born at 41 weeks 5 days gestation. The baby was reported as normal with no congenital anomalies. The baby weighed 9 pounds 1 ounce, 12 inches in length, had apgar score of 7 at one minute of life and 9 at five minutes of life. It was reported that the baby was admitted to the neonatal intensive care unit for respiratory distress. No further information is available. The mother's adverse experience has been captured in WAES# 0903USA01999.

Other Meds: Influenza virus vaccine; Vitamins (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **373096-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Dec-2009	11-Dec-2009	0	14-Dec-2009	14-Dec-2009	MD		14-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU(H1N1)	SANOFI PASTEUR	UP013AA	0	Left arm	Intramuscular	
HEPA	MERCK & CO. INC.	1100Y	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0087Y	2	Right arm	Intramuscular	
FLU	SANOFI PASTEUR	500745P	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Syncope, Throat irritation, Tinnitus

Symptom Text: Patient to lab for blood draw post vaccine, syncopal episode outside lab, patient alert c/o abdominal pain, ringing in ears, throat "feels like bleeding". Patient stayed at office for observation x30 minutes v/s monitored, patient denied sx and released home with parent.

Other Meds:

Lab Data: None

History: Eczema, family hx asthma

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **373181-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	11-Dec-2009	12-Dec-2009	1	14-Dec-2009	15-Dec-2009	CO		13-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672P	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling

Symptom Text: 10 1/2 yr. with 36 hours of getting vaccine. Injection site swollen to size of softball, resolved w/ in 48 hours. No redness.

Other Meds:

Lab Data:

History: Short stature; Monilia

Prex Illness:

Prex Vax Illns:

Vaers Id: **373314-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	U	Unknown	Unknown		15-Dec-2009	16-Dec-2009	--	WAES0912USA00907	16-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a consumer who saw a report on the internet about a 23 year old patient who was vaccinated with 3 doses of GARDASIL. Subsequently the patient died, the cause of the death was unknown. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **373315-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Dec-2009	16-Dec-2009	--	WAES0912USA01166	16-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a consumer who saw a report on the internet concerning two patients (unspecified ages) who were vaccinated with 3 doses of GARDASIL (dates were not reported). Subsequently the patients died, the cause of death was unknown. This is one of several reports received from the same source. This is a hearsay report, attempts are being made to obtain identifying information to distinguish individual patients. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **373332-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		15-Dec-2009	16-Dec-2009	FR	WAES0912USA01104	16-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Fall, Hypotension, Malaise, Presyncope, Shock, Syncope

Symptom Text: Serious case received from a health care professional (physician). A 17 year old female patient received a third dose of GARDASIL, batch number not reported. She fainted and fell on the ground, twice. She was sent to the hospital for a vagal shock/vagal malaise. During the first malaise, she had hypotension. During the second malaise, her glycemia was 50 despite having had breakfast. Other business partner numbers include E2009-11257.

Other Meds: None

Lab Data: blood pressure measurement, hypotension; blood glucose, 50

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **373334-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	24-Nov-2009	26-Nov-2009	2	15-Dec-2009	16-Dec-2009	FR	WAES0912USA01414	16-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoacusis

Symptom Text: Information has been received from Health Authority (107782) (local case#: IT580/09), concerning a 19 year old female who was vaccinated on 24-NOV-2009 with one dose of GARDASIL (dose, route and batch number not reported). It was also reported that the patient suffers from neurosensorial congenital deafness for which she wears a hearing aid. On 26-NOV-2009, she presented with sudden hypoacusis. An ear, Nose & Throat (ENT) consultant was requested (NOS). At the time of reporting the patient had improved. The case is closed. Other business numbers included E2009-11209. Hypoacusis was considered to be an other important medical event by the reporter. No further information is available.

Other Meds: unknown

Lab Data: unknown

History:

Prex Illness: Deafness congenital

Prex Vax Illns:

Vaers Id: **373335-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Feb-2009	05-Feb-2009	1	15-Dec-2009	16-Dec-2009	FR	WAES0912USA01449	16-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0747X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Solar urticaria, Vaccine positive rechallenge

Symptom Text: Case received from the Health Authorities under the reference number L200911792 on 30-NOV-2009: This case may be a duplicate of a non serious case E2009-02047 but no confirmation was obtained to date. A 16 year old female patient with medical history of vertiginous syndrome had received the first dose of GARDASIL (batch # NJ040530, lot # 0747X) via intramuscular route on 04-FEB-2009. On 05-FEB-2009 the patient presented with urticarial reaction on the parts of the body exposed to the sun (including face). Event maintained without recovery (clarification has been requested). The patient received a corrective treatment with desloratadine, dimetindeno, hydroxysine, dexamethasone and ebastine 10 mg. On 22-APR-2009, the patient received the second dose of GARDASIL (batch # NJ46700, lot # 0773X) and she experienced the same urticarial reaction. The reaction persisted without recovery. The Health Authorities considered the case as 'other medically important condition'. Other business partner numbers include: E2009-11415.

Other Meds: Unknown

Lab Data: Unknown

History: Vertiginous disorder

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **373610-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Dec-2009	08-Dec-2009	0	16-Dec-2009	16-Dec-2009	PA		17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	U2937CA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	0672Y		Left leg	Intramuscular	
	HPV4	MERCK & CO. INC.	U3029AA		Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscular weakness, Myalgia, Nausea, Pallor, Pyrexia

Symptom Text: Patient received ADARIEL, GARDASIL, and MENACTRA on 12/8. Shortly after became nauseated and pal. Rested and took juice-felt better. On 12/10 parent called- patient feel her arms and legs feel "gooey". Had fever on 12/9. Achy muscles-not free weakness. Also has persistent nausea.

Other Meds:

Lab Data:

History:

Prex Illness: Mild URI

Prex Vax Illns:

Vaers Id: **373625-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Nov-2009	15-Nov-2009	2	16-Dec-2009	16-Dec-2009	KY		17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3017AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0100Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Back pain, Headache, Neck pain, Rash pruritic

Symptom Text: generalized pruiritic raised rash to arms, back, abd, and legs accompanied by neck/back/shoulder/knee/head pain

Other Meds: Depo-provera on 09/29/2009

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

Vaers Id: **373636-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-May-2009	01-May-2009	0	16-Dec-2009	17-Dec-2009	--		28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Ataxia, Fatigue, Headache, Pyrexia, Tachycardia

Symptom Text: This 18 year old female received the GARDASIL vaccine and 2 weeks later developed acute disseminated encephalomyelitis. Her initial symptoms were fever tachycardia and headache followed by ataxia. She was discharged and had a recurrence of her symptoms a month later which resolved over the following weeks. She has been left with persistent fatigue and intermittent tachycardia.

Other Meds: None

Lab Data: She had a normal lumbar puncture and an abnormal MRI with two periventricular white matter lesions.

History: Allergies PanMist SM SYRP. Active Problems Normal Routine History And Physical Adult -V70.0 - PMH Eczema -692.9. Family Hx No multiple sclerosis No stroke syndrome No paraplegia of unknown etiology No autoimmune disease. Personal Hx Behavioral history: Not smoking. Alcohol: Not using alcohol. Drug use: Not using drugs. Marital History - Single.

Prex Illness:

Prex Vax Illns:

Vaers Id: **373637-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
-0.8	U	21-Jul-2008	20-Aug-2008	30	16-Dec-2009	17-Dec-2009	--	WAES0810USA02706B1	17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gastrooesophageal reflux disease, Labour complication

Symptom Text: Information has been received from a nurse, for the Pregnancy Registry for GARDASIL, concerning a baby whose mother was vaccinated with a first dose of GARDASIL (Lot# 660553/0070X) on 21-JUL-2009 and on 18-SEP-2008 was vaccinated with a second dose of GARDASIL (660616/0570X). The baby's mother LMP was on 20-AUG-2008. It was reported that the baby was born via c-section on 09-JUN-2009 (WAES# 0810USA02706). The baby's birth weight was 6 lbs 11oz. The nurse indicated that the baby had "intolerance to the labor" and problems with gastroesophageal reflux disease but otherwise "was a well baby, no congenital anomalies". At the time of this report, the outcome of the baby was unknown. Upon internal review intolerance to labor was considered to be an other important medical event. Additional information is not expected.

Other Meds: MACROBID; EFEXOR; Vitamins (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **373638-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Sep-2009	28-Sep-2009	0	16-Dec-2009	17-Dec-2009	--	WAES0910USA03106	17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Pregnancy test urine positive

Symptom Text: Information has been received from a physician assistant, for GARDASIL, a Pregnancy Registry product, concerning a 15 year old female patient with AMOXICILLIN and PENICILLIN allergies and no medical history who on 28-SEP-2009 was vaccinated with the first 0.5ml dose of GARDASIL (lot# 661531/1311X) in the left arm. Concomitant therapy included FLUMIST intranasal. On 16-OCT-2009, the patient was seen for a regular check up and her blood was drawn. The physician assistant reported that the patient must had thought the blood work was a pregnancy test because she told her mother she was pregnant. On 22-OCT-2009, the patient and her mother came to the clinic. Urine pregnancy test was taken with a positive result. Her LMP was 28-AUG-2009. Expected date of delivery was 04-JUN-2010. The patient was not experiencing any adverse effects. At the time of the report, the patient's outcome was unknown. Follow-up information has been received from a physician assistant who reported that the patient experienced a miscarriage on 07-NOV-2009. At the time of the report, the patient's outcome was unknown. Upon internal review, miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: urine beta-human, 10/22/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = 8/28/09); Penicillin allergy; Penicillin allergy

Prex Vax Illns:

Vaers Id: **373642-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	04-Dec-2009		16-Dec-2009	17-Dec-2009	--	WAES0912USA01170	17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Electroencephalogram

Symptom Text: Information has been received from a laboratory technician concerning a 21 year old female patient who was vaccinated with her initial dose of GARDASIL in 2009 a few months ago (date unspecified). Subsequently the patient experienced a seizure of unknown etiology on 04-DEC-2009 "four days ago" (from time of reporting). She had an electroencephalography (EEG) and was awaiting the results. The patient had sought medical attention at office. The outcome of the event was unknown at the time of this report. Upon internal review, seizure of unknown etiology was determined to be an other important medical event. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **373645-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Nov-2009	11-Nov-2009	0	16-Dec-2009	17-Dec-2009	FR	WAES0912USA01539	17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ37700	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Confusional state, Loss of consciousness, No reaction on previous exposure to drug, Tonic clonic movements

Symptom Text: Information has been received from a Health Agency (Case No. 107870), concerning an 11 year old female who was vaccinated on 11-NOV-2009 with the third dose of GARDASIL (Lot No. NJ37700) via intramuscular route. On the same day, a few minutes post-vaccination, she presented with generalized tonic-clonic jerks accompanied by loss of consciousness (lasting a few seconds), followed by slight confusional state and amnesia of the event. She was laid down with her lower limbs raised, her vital signs (blood pressure and cardiac frequency) were monitored and were within normal range. She was held for about 80 minutes. The event resolved in a few minutes. It was also reported that the patient did not experience any adverse effect after the 2 previous doses of GARDASIL. The event was reported as not serious by both Health Agency and the reporter and upgraded to serious by the Company. To note, Health Authority and coded only "tonic-clonic" epilepsy. The outcome is recovered on 11-NOV-2009. Case is closed. The originally reporting source was unknown. Other business partner numbers include E2009-11213. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 373648-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Nov-2009	11-Nov-2009	6	16-Dec-2009	17-Dec-2009	FR	WAES0912USA01541	17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Asthenia, Complex partial seizures, Depressed level of consciousness, Eye movement disorder, Headache, Loss of consciousness, Neurosensory hypoacusis, Tonic convulsion

Symptom Text: Information has been received from Health Authority (reference number ES-AGEMED-908461236) on 10-DEC-2009 concerning a 14 year old female patient who on 05-NOV-2009 was vaccinated with a dose of GARDASIL (lot#, route, site of administration not reported). It was reported that after vaccine administration, the patient presented a deterioration of consciousness presenting rhythmic oscillating ocular movements, tonic movements in right upper limb, distal movements in lower limbs and loss of consciousness (GSC<8). In the emergency room she recovered consciousness presenting with amnesia of the episode, headache and generalized weakness. Afterwards, during the patient's hospitalization (hospitalization date not reported), she showed a satisfactory evolution and was discharged without symptoms (discharge date not reported). A magnetic resonance imaging (MRI), electrocardiogram (EKG) and electroencephalography (EEG) (date not reported) were performed without findings. Left neurosensory hypoacusis was observed, possibly related with an auditory neuropathy. Neurosensory hypoacusis and complex partial seizures were considered to be other medically important events by the reporter. Other business partner number included: E200911419. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, without findings; electrocardiogram, without findings; electroencephalography, without findings

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **373657-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2009	01-Jun-2009	0	16-Dec-2009	17-Dec-2009	FR	WAES0912RUS00002	17-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK41620		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Disability, Pain in extremity

Symptom Text: Information has been received from a physician concerning a female who in June 2009, was vaccinated with GARDASIL. In June 2009, the patient experienced arm pain. In September 2009, the patient recovered from arm pain. The reporter felt that arm pain was related to therapy with GARDASIL. Arm pain was considered to be disabling. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **373658-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	10-Dec-2009	Unknown		16-Dec-2009	16-Dec-2009	KY		08-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1350Y	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	UP3394AA	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Discovered patient was pregnant after HPV vaccine given - patient was seen for family planning visit. Provider ordered HPV vaccine & flu vaccine "today". Vaccines were given at 3:05pm as ordered.

Other Meds: None

Lab Data:

History: NKDA

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **373689-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	M	03-Dec-2009	04-Dec-2009	1	16-Dec-2009	17-Dec-2009	RI		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1333Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site pain, Myalgia, Pain

Symptom Text: site painfule immediate after injection, pain has persisted; no throbbing or redness, pain with movement; developed right trapezius pain, still present on 12/15/09

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: 373827-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	M	09-Oct-2008	12-Aug-2009	307	17-Dec-2009	18-Dec-2009	NY	WAES0911USA01240B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Gastroschisis, Intensive care, Premature baby, Small for dates baby

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL concerning a 22 year old female with bacterial vaginosis who was vaccinated intramuscularly with the first 0.5 dose of GARDASIL in the left upper arm in August 2008 her first month of previous pregnancy, reported in (WAES # 0809USA00445), the second dose of GARDASIL in her right upper arm in October 2008 with no other vaccines was given on this date and the third dose of vaccine on her left arm on 04-NOV-2009. Concomitant therapy included 250 mg FLAGYL for bacterial vaginosis infection, folic acid 3 weeks after the visit and the flu vaccine in her right arm. The patient delivered a male child by caesarean section due to gastroschisis 3 months ago. Child had complication gastroschisis, abdominal defect, which required surgery and longer stay at the hospital after birth. Child was being seen by specialist. Follow up information was received from the physician concerning the patient with no obstetric history as well as no medical history or concurrent conditions who was vaccinated with her first, second and third dose of GARDASIL on 05-AUG-2008, 09-OCT-2008 and 04-NOV-2009 respectively. Concomitant therapy included FLAGYL folic acid from 07-AUG-2008 and influenza virus vaccine on 04-NOV-2009. Amniocentesis indicated that the patient was 4.5 months pregnant (LMP: 12-AUG-2008; EDD: 19-MAY-2009). The results of the amniocentesis were "negative". On 12-AUG-2009, at 25 weeks of gestation, the patient delivered an abnormal male baby weighting 4 pounds, 18 cm in length with head circumference of 35. The baby was born by caesarean section with gastroschisis. The mother had not complication during pregnancy and needed caesarean section because of the baby's gastrochisis. The mother did not experience any infections or illnesses during pregnancy. The infant was still in NICU as of today. Other medication used during this pregnancy included prenatal vitamin, 1 tablet, daily. Follow up information was received from the physician via telephone

Other Meds: Folic acid; FLAGYL

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **374021-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	15-Dec-2009	15-Dec-2009	0	17-Dec-2009	18-Dec-2009	CA		18-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Extreme headache on my whole head. Not a sharp pain. Just a constant pain, not throbbing. When I bent my head down it would hurt a little more for a minute. Just a painful and very annoying headache that lasted through 12-17-2009 (today). When I took 2 Excedrin it helped a lot.

Other Meds: Currently taking Ocella, have been since April 2007

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: None noticed~HPV (Gardasil)~1~0.00~Patient|None noticed~HPV (Gardasil)~2~0.00~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **374072-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Dec-2009	16-Dec-2009	0	18-Dec-2009	18-Dec-2009	PA		02-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1378Y	3	Left arm	Intramuscular	FLU HEP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: M.A. misinterpreted order for Hep B and administered GARDISIL (HPV) vaccination. PCP notified - no harm to patient

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **374122-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Dec-2009	14-Dec-2009	0	18-Dec-2009	18-Dec-2009	PA		21-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3079AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1013Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Loss of consciousness

Symptom Text: Patient passed out. No injury. Decreased BP.

Other Meds:

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **374177-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	06-Oct-2009	07-Oct-2009	1	18-Dec-2009	21-Dec-2009	NV		21-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLLA283AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0671Y		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling, Eyelid oedema

Symptom Text: Pt stated on 12/17/09 office visit that 24 hours after receiving both GARDASIL and Influenza she developed swelling around (L) eye, included the upper lid, this resolved within 24 hours, no care was sought, no measures were taken for this, no MD was contacted.

Other Meds:

Lab Data: None

History: NKDA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **374240-1** **Related reports:** 374240-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Aug-2008	Unknown		20-Dec-2009	21-Dec-2009	VA		03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Nausea, Rash erythematous, Rash pruritic

Symptom Text: joint pain and red itchy rash started and have continued for over a year. She had nausea directly after the shots for a few weeks.

Other Meds:

Lab Data: seeing a derm in january 2010. Saw an orthopedist in fall of 2008 who said it was from low cartilidge. She has had that her whole life and never had pain until the shot.

History: prev nickel allergy when she was little, had not bothered her in a long time though.

Prex Illness: no illness before, after she had nausea constantly for a few weeks.

Prex Vax Illns:

Vaers Id: **374240-2** **Related reports:** 374240-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Jun-2008	01-Sep-2008	77	28-Dec-2009	28-Dec-2009	VA		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Dermatitis atopic, Exfoliative rash, Induration, Osteochondrosis, Pain, Palpitations, Patellofemoral pain syndrome, Pharyngitis, Pruritus, Rash, Rash erythematous, Rash papular, Scab, Tenderness, Upper respiratory tract infection, Viral infection

Symptom Text: Started with an itchy painful rash on leg and it has spread all over leg and on arms. Treated with hydrocortisone and then with an antifungal over the last year. Still spreading. Her joint pain began with her knees, and now she has pain in all joints incl ankles, wrists, fingers, elbows and hip. No treatment. She has been complaining of an occasional racing heartbeat and palpitations. cant find how to list all dates of shots on here, they are 6/16/08 lot 1267U 8/18/08 0072X 12/23/08 lot 1061U. 12/29/09 pt continuity code with 374340. ```12/29/09 Received PCP medical records. 12/23/08 visit for pruritus w/ rash & erythematous patch which was scaly, tender & hard. Crusts were seen. Dx w/atopic eczematous dermatitis. HPV & flu vaccines given. Tx w/oral anti itch med & steroid cream. 2/12/09 visit for sore throat, nasal congestion, cough x 1 wk. Rash reported since 9/08. Dx w/rash & pharyngitis. Tx w/antibiotic as suspected rash due to previous strep infection. 10/13/09 visit for HA, bilat earache, myalgias, fever, cough, nasal congestion, sore throat x 4 days, intermittent fever, vomiting. Dx w/viral syndrome & URI. Ortho consult of 10/29/08 reveals patient experienced bilat knee pain x several mo which had progressed severely in week prior. Dx w/patellofemoral chondrosis. PCP exam 12/10/09 revealed erythematous papular rash. Referred to Derm. 12/20/09 Seen for itchy rash on arms & legs x 1 yr. No improvement w/steroid cream. 12/28/09 Office rec t/c from parent to report rash & joint pain since 2008, flares after hot shower & never completely resolved. ```1/11/10 Received vaccine records & duplicate PCP medical records.

Other Meds:

Lab Data: none at this time. have appts in Jan and Feb 2010 with pediatrician, orthopedist and dermatologist ```12/29/09 Recieved PCP medical records w/LABS: influenza A&B neg. Strep test neg.

History: Allergy to nickel ```12/29/09 Received PCP medical records w/PMH: Allergy: pencillin.

Prex Illness: After vaccine she was nauseated for several days.

Prex Vax Illns:

Vaers Id: 374319-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Dec-2009	17-Dec-2009	0	21-Dec-2009	21-Dec-2009	KY		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	08194	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Complicated migraine, Headache, Hemiparesis, Hypoaesthesia, Lethargy, Nausea, Paraesthesia, Vaccination complication, Vision blurred

Symptom Text: Mom called 12/21/09-states child received 3rd HPV vaccine on 12/17/09 8 AM-that night child was taken to ER with H/A, lethargic, numbness and tingling in (L) arm and leg and chest pain (L) side, vision blurred. States had CT scan that was neg. and bloodwork. Then sent to another hospital-was there about 12 hrs then sent home. Pt. had been having H/A's for the last 2-3 months. ```12/21/2009 ED records for 12/17/2009 Impression: adverse reaction to vaccine patient with c/o's headache, chest tightness, arm numbness, lt sided weakness, nausea and blurred vision, dx studies and labs negative, patient transferred to another facility " for lack of Dx" ```1/28/2010 ED records for 12/18/2009 dx paresthesia complicated migraine, tx oxycodone and fluids

Other Meds: none

Lab Data: CT scan; bloodwork ```12/21/2009 ED records for 12/17/2009 Impression: adverse reaction to vaccine labs cbc, cmp dx studies: ekg, ct head both wnl ```1/28/2010 ED records for 12/18/2009 dx paresthesia complicated migraine, tx oxycodon

History: none ```12/21/2009 ED records for 12/17/2009 Impression: adverse reaction to vaccine pmh: none allergies: nkda ```1/28/2010 ED records for 12/18/2009 dx paresthesia complicated migraine, tx oxycodone and fluids

Prex Illness: none ```12/21/2009 ED records for 12/17/2009 Impression: adverse reaction to vaccine ```1/28/2010 ED records for 12/18/2009

Prex Vax Illns:

Vaers Id: 374323-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
-0.7	M	04-Feb-2008	21-May-2008	107	21-Dec-2009	22-Dec-2009	--	WAES0807USA03163B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	1	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Cleft lip and palate, Congenital anomaly, Drug exposure during pregnancy, Myringotomy

Symptom Text: Information has been received from a health professional, for the Pregnancy registry for GARDASIL, concerning a male baby patient whose 24 year old mother with tobacco use and a history of 1 pregnancy and 1 live birth was vaccinated intramuscularly with the first, second and third 0.5 ml doses of GARDASIL on 03-DEC-2007, 04-FEB-2008 and 04-JUN-2008, respectively (lot # of the 2nd dose: 655327/1287U; lot # of 3rd dose: 655604/0052X). There was no concomitant medication. The mother was two weeks pregnant while receiving the third dose of GARDASIL. The pregnancy test was positive. On 23-SEP-2008, ultrasound was performed with normal result. On 15-OCT-2008, maternal serum alpha-fetoprotein (MSAFP) was performed with negative result. On 13-FEB-2009 (Weeks from LMP: 39), the baby was born with congenital anomaly cleft palate, weight: 8 pounds 3 oz and Apgar score 8/9. As of 01-JUL-2009, the outcome of cleft palate was unknown. Follow-up information was received from a nurse who reported that the baby was born with congenital anomaly cleft palate and cleft lip, height: 22 inch. The baby visited a cleft craniofacial center on 18-FEB-2009 and visited an audiology center on 09-JUN-2009. At the time of reporting, the outcome of cleft palate and cleft lip were unknown. Follow-up information was received from a nurse via medical records indicating that the baby's Apgar was 8 at 1 minute, 9 at 5 minutes. Birth weight was 8 pounds and 5 ounces. He failed the newborn hearing screen of the left. The baby was born with cleft lip unilateral complete and cleft palate unilateral complete. On 25-FEB-2009, the infant was 12 days old. This was a well visit. It was noted that the cleft lip and palate would be repaired when the child was 4-6 months of age. On 04-SEP-2009 the patient had cleft lip repaired and had myringotomy with tubes. On 17-NOV-2009 the patient presented for a scheduled 9 months well child visit. He had ear tubes. Physical exam showed tympanic membranes normal landmarks, no fluid or erythema bilaterally. At the time of

Other Meds: Unknown

Lab Data: Hearing test, Newborn hearing screen; failed--left; Apgar score, 02/13/09, 8/9

History:

Prex Illness: Tobacco user

Prex Vax Illns:

Vaers Id: 374324-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Jan-2008	26-Mar-2008	77	21-Dec-2009	22-Dec-2009	--	WAES0912USA01364	28-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U		Unknown	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Back pain, Bedridden, Bowel movement irregularity, Constipation, Diarrhoea, Diplegia, Fall, Haematochezia, Haemorrhoids, Hypoaesthesia, Mass, Nausea, Ovarian cyst, Pain, Staphylococcal infection, Swelling, Syncope, Tachycardia

Symptom Text: Information has been received from a physician's administrator, a registered nurse, a medical assistant and a consumer concerning her 17 year old daughter with seasonal allergies and allergy to BENADRYL and BACTRIM who on 14-MAR-2007 was vaccinated with a first 0.5 ml dose of GARDASIL (Lot No. 655618/0186U) administered in her left arm. On 09-JUL-2007 the patient received a second dose of GARDASIL (Lot No. 654272/0319U) administered in her right arm and on 09-JAN-2008 received a third dose of GARDASIL (Lot No. 657872/0515U) administered on her left arm. Concomitant medication included NUVARING. On 26-MAR-2008 the patient developed a "bump" on her thigh. In June 2008 the patient developed a MRSA infection, confirmed on 29-SEP-2008. On 02-JUL-2008 the patient experienced bowel movement issues. The patient's mother mentioned that the patient is in constant pain which she described as 6 on a scale of 1-10. She also had periodic paralysis of her lower extremities and her "muscles go numb and she falls all the time". She had abdominal pain and nausea and had developed ovarian cysts. The patient saw a pediatric surgeon for her ovarian cysts. The physician's administrator indicated that the condition had "nothing to do" with GARDASIL. The mother mentioned that the patient was almost completely bedbound. It was reported that the patient's boyfriend had a breakout of MRSA on 17-FEB-2009. The medical assistant stated that in March 2009 the patient was seen for the last time after a "well check-up". The patient was hospitalized twice in the summer of 2009 for an unknown reason (length of stay unspecified). The patient had been to the neurologist and had tests done on her muscles and her bones and no one could "figure out what's wrong with her". The medical assistant did not have any information surrounding the patient's paralysis, ovarian cysts, or hospitalizations. Bone scan, colonoscopy, CT scans and MRI tests were performed with no results provided. On 18-NOV-2009 the patient was seen by a neurologist. An EMG was done alo

Other Meds: NUVARING

Lab Data: Bone scan, no results provided; colonoscopy, no results provided; computed axial, no results provided; magnetic resonance, no results provided; electromyography, 11/18?/09, patient was stable and no neurological symptoms were noted ```DX

History: ```PMH: sacral teratoma, fallopian tube cyst. Allergies: Bactrim.

Prex Illness: Seasonal allergy; drug hypersensitivity

Prex Vax Illns:

Vaers Id: **374332-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-May-2009	06-Jun-2009	21	21-Dec-2009	22-Dec-2009	MA	WAES0912USA01612	22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthritis, Psoriatic arthropathy, Steroid therapy, Wheelchair user

Symptom Text: Information has been received from a physician concerning her 12 year old daughter who on 05-MAR-2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot # unknown) and concomitantly received (DTaP) (manufacturer not reported). On 16-MAY-2009, the patient received the second dose of GARDASIL (lot # unknown) with no concomitant vaccinations administered at that time. On 19-SEP-2009, the patient received the third dose of GARDASIL (lot # unknown) with no concomitant vaccinations administered at that time. Three weeks after the patient's second dose of GARDASIL on approximately 06-JUN-2009, she developed chronic arthritis and was seen by an orthopedist (name of orthopedist not reported) for arthritis-type symptoms. The patient was placed on MOTRIN. The patient developed psoriatic arthritis and initially needed a wheelchair. The patient was seen by a rheumatologist affiliated with a hospital. The patient had an MRI and a bone scan and was diagnosed with psoriatic arthritis. The patient was placed on sulfasalazine and therapy with prednisone for six weeks. The patient was not hospitalized. Within 2 days after starting the medications the patient's symptoms had resolved. The patient was back to her normal activities. The rheumatologist was definitely related to GARDASIL and the physician thought her daughter's arthritis was related to receiving GARDASIL. Psoriatic arthritis was considered to be disabling by the physician. The Health Care professional contacted during telephone follow-up could not supply the following information: lot number. No further information is available at this time. Additional information has been requested.

Other Meds:

Lab Data: Magnetic resonance, diagnosed with psoriatic arthritis; bone scan, diagnosed with psoriatic arthritis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **374526-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Aug-2009	04-Aug-2009	0	21-Dec-2009	22-Dec-2009	KS	KS200914	22-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1497X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB350AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3097AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Pt. came to Health Dept. on 8-4-09 with mom to get vaccinations. Pt and mom returned to Health Dept. on 10-8-09 for proof of pregnancy. According to time of last menstrual period, she would have been about 3 weeks pregnant, but unaware at time of vaccine admin.

Other Meds: None Known

Lab Data: None

History: None Known

Prex Illness: None ? pregnancy more or less 3 weeks

Prex Vax Illns:

Vaers Id: **374578-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	20-Oct-2009	20-Oct-2009	0	21-Dec-2009	22-Dec-2009	CA		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site anaesthesia, Injection site pruritus

Symptom Text: Patient stated that developed itching at injection site, she scratched site and then site became numb.

Other Meds: DEPO PROVERA

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **374620-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Dec-2009	21-Dec-2009	0	22-Dec-2009	22-Dec-2009	CA		22-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3048AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3249AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Vertigo, Vision blurred

Symptom Text: 11;45 a.m. blurred vision, dizziness, vertigo. 11:46 am black out

Other Meds: no

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: 374741-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	21-Jun-2008	01-Oct-2008	102	22-Dec-2009	23-Dec-2009	FL	FL	25-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal tenderness, Acne, Activities of daily living impaired, Alopecia, Back pain, Decreased appetite, Depression, Diarrhoea, Dizziness exertional, Dyspnoea, Enteritis, Fatigue, Feeling abnormal, Heart rate increased, Hypertrichosis, Migraine, Nausea, Neck pain, Weight increased, Weight loss poor

Symptom Text: My entire life I have been very active, worked out every day of my life since 15, never ever in my life had any sort of acne...no health problems. About a year ago everything changed, in the past year I have gained exactly 27 pounds and although I continue and try to workout I am unable to lose this weight...I am so fatigued to the point I cant get out of bed most days which has affected a few semesters of college and I have lost a few jobs due to this fatigue which I cannot control. I am unable to bend over and pick anything up without getting dizzy and any activity as simple as running up the stairs my heart speeds up and I am out of breath and need to sit. I have consistently had a minimum of 2 migraines a week in which I am unable to leave the house this has been for the past year, and prior to these migraines I have extreme back and neck pain which painkillers cannot even help. I have been to numerous dermatologists trying to resolve 2 issues, adult acne AND excessive facial hair growth on my jawline, chin and under chin to the point Ii just use a razor now to remove the hair as I am unable to afford full laser hair removal and insurance does not cover. My entire life I have had beautiful thick hair, in fact so thick I would get stopped by people with compliments however the past year I pull chucks of hair out in the shower and it is very thin and brittle now. I have done so much blood work and every test in the book. In the past year I have been to a heart doctor, dermatologists, chiropractors, endocrinologist, natural homeopathic doctor, and 3 different physicians and NO ONE has a solution...my mom has been very down as she is upset for me and with me we feel so lost nobody has any idea what is going on. The past year I have consistently described myself as "this is not me and this is not my body". I now get depressed as I have no control of the weight gain or acne or facial hair or hair loss or any of this. My numerous doctor visits and mental pain I have endured have left a hole in my family's w

Other Meds:

Lab Data: Have been tested for PCOS as I have all of the symptoms for it but 3 different doctors ran tests including an endocrinologist and it has been confirmed 3 times that I do not have PCOS. All of these symptoms have occurred exactly after my 1

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **374742-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Dec-2009	22-Dec-2009	0	22-Dec-2009	23-Dec-2009	PA		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1397Y	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0381Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Excoriation, Loss of consciousness

Symptom Text: Patient was standing for injections Gardisal #3 administered in L.A. then Hep A #2 administered in R.A. About 2 minutes after receiving injections, patient stated "Can't see" and passed out. Mom and I helped her to the floor. Patient aroused in a few seconds was helped to table. BP was 114/68. Patient did have breakfast this AM. Received small 1/2 inch superficial abrasion on left elbow. Cleansed with sterile water and gauze, neosporin and bandaid applied. Patient moved to sitting position BP 118/62. Patient moved to standing position. Patient able to walk out of office, no dizziness, feeling fine.

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **374774-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Dec-2008	01-May-2009	135	22-Dec-2009	23-Dec-2009	FR	WAES0912USA02181	23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Henoch-Schonlein purpura

Symptom Text: Information has been received on 14-DEC-2009 from the Health Authority (ESAGEMED-519193347) concerning a 13 year old female patient with no other relevant history reported who on 17-DEC-2008 was vaccinated intramuscularly with a 0.5ml dose of GARDASIL (lot # and site of administration not reported) and a 0.5ml dose of RECOMBIVAX HB (MSD) (lot # and site of administration not reported, thimerosal free). In May 2009, the patient developed Schoenlein-Henoch purpura. At the time of this report, the patient had not recovered. Schoenlein-Henoch purpura was considered to be an other important medical event by the Health Authority. Other business partner numbers included: E2009-11583. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **374775-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	M	04-Dec-2008	13-Jul-2009	221	22-Dec-2009	23-Dec-2009	WV	WAES0812USA01628B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amino acid level normal, Drug exposure during pregnancy, Hydrocele, Laboratory test normal, Metabolic function test normal

Symptom Text: Information has been received via pediatric medical records from a physician concerning a newborn patient with passive smoke risk who's mother was vaccinated IM on 04-Dec-2008 with a 0.5ml first dose of GARDASIL while pregnant (WAES#0812USA1628). It was reported that on 13-JUL-2009, at the age of 3 days, the baby underwent an ultrasound test in order to investigate a scrotal mass. The ultrasound revealed moderate right sided hydrocele. The baby's testicles appeared to be normal with the right testicle measuring 1cm and the left testicle 9mm. Arterial flow was noted in both testicles. The epididmyides appear normal. On 13-JUL-2009 the following test results were obtained: blood lymphocyte count 25.0%, blood segmented neutrophil count 65.0%; blood band neutrophil count 4%, slight anisocyte observation, slight poikilocyte observation, slight polychromatic erythrocyte observation, slight macrocyte observation. Also performed on this day were congenital hypothyroidism, hemoglobinopathy, galactosemai, biotinidase deficiency, congenital adrenal hyperplasia, cystic fibrosis, amino acid profile, fatty acid profile and organic acid profile. All reported as normal. The baby was seen for multiple well visits where the genitalia was reported as normal. At the time of this event, the patient recovered from Hydrocele. No further information is available. All available medical records will be provided upon request.

Other Meds: Unknown

Lab Data: ultrasound, 07/13/09, see narrative; anisocyte, 07/13/09, slight; band neutrophil count, 07/13/09, 4 %; lymphocyte count, 07/13/09, 25 %, low; segmented neutrophil, 07/13/09, 65 %, high; macrocyte, 07/13/09, slight; poikilocyte, 07/13/09, s

History:

Prex Illness: Passive smoking

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **374776-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Dec-2009	23-Dec-2009	--	WAES0912USA01611	23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a female patient who was vaccinated with a dose of GARDASIL (no lot number provided). At "some point in the past" after receiving GARDASIL, the patient became pregnant and subsequently experienced miscarriage. At the time of reporting, the outcome was unknown. The patient sought unspecified medical attention. Upon internal review, miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **374777-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	M	Unknown	08-May-2009		22-Dec-2009	23-Dec-2009	TN	WAES0908USA03124B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Cardiac septal defect, Congenital anomaly, Cough, Diarrhoea, Drug exposure during pregnancy, Ear pain, Hyperbilirubinaemia, Irritability, Jaundice, Upper respiratory tract infection

Symptom Text: Information has been received from a respiratory therapist, pediatrician, nurse and office assistant via pediatric medical records concerning a newborn male patient with no known drug allergies who was born on 04-MAY-2009 by C-section (WAES# 0908USA03124). It was reported that on August 2008, the mother was vaccinated with a dose of GARDASIL (lot not reported) while pregnant. According to the reporter, the patient was born with "3 holes in his heart". It was unknown if the patient and her baby sought medical attention. The respiratory therapist stated that her baby was "doing OK right now". Nurse did confirm patient had a caesarian delivery on 04-MAY-2009 and he was a healthy male child. On 07-May-2009, a direct bilirubin test was performed with results of 0.23. Also on this day a blood urea nitrogen was performed with results of 7 and a total bilirubin was performed with results of 8.39. On 08-MAY-2009, a total bilirubin (7.73), direct bilirubin (0.19) and indirect bilirubin (7.54) were performed. There was no concomitant medication reported. It was reported that on 11-May-2009 that the baby experienced jaundice. According to the office assistant who pulled the baby's chart it was reported that at the office they had a report verbal only, noted in the chart from the pediatric cardiologist. It was reported that the baby was seen on 17-May-2009 and had a septal defect. The reporter stated that the cardiologist was going to "give it time to see if it was self-correcting, and scheduled a follow-up evaluation for the baby in six months". At that day the physician's office did not have any follow-up evaluation from the cardiologist. The office assistant provided cardiologist information. On 29-May-2009, the patient had a well child visit with no complaints. On 02-June-2009, the baby was seen for loose stools and fussiness. On 10-JUL-2009, the patient had his 2 month well child visit. On 31-JUL-2009 the baby was seen for upper respiratory infection and cough, which resolved on approximately 14-AUG-2009. On 21-AUG-2009

Other Meds: Unknown

Lab Data: Total serum bilirubin, 05/07/09, 8.39 mg/d; Total serum bilirubin, 05/08/09, 7.73 mg/d; Serum direct bilirubin, 05/08/09, 0.19mg/d; Serum indirect 05/08/09, 7.54mg/d; Serum direct bilirubin, 05/07/09, 0.23mg/d; Respiratory rate, 28; tempera

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **374780-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	U	Unknown	Unknown		22-Dec-2009	23-Dec-2009	FR	WAES0912USA02326	23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Autoimmune disorder, Death

Symptom Text: Information was reported in a newspaper article that a 14 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL vaccine (lot number, date, route and site not reported). Subsequently the patient experienced auto-immune symptoms and died 21 months later. The article also discussed the multiple sclerosis of other 5 patient while on therapy with GARDASIL vaccine (WAES 0912USA01664, WAES 0912USA02322, WAES 0912USA02323, WAES 0912USA02324, and WAES 0912USA02325, WAES 0912USA02639, WAES 0912USA02640, WAES 0912USA02641, WAES 0912USA02642 and WAES 0912USA02643. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 374854-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	25-Sep-2009	16-Nov-2009	52	23-Dec-2009	23-Dec-2009	CA		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Right arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Autoimmune thrombocytopenia, Blood product transfusion, Contusion, Cough, Diarrhoea, Dyspnoea, Epistaxis, Fatigue, Feeling hot, Haematochezia, Hypoaesthesia, Idiopathic thrombocytopenic purpura, Injection site pain, Lip disorder, Migraine, Monoplegia, Muscular weakness, Oral contraception, Paraesthesia, Petechiae, Respiratory tract congestion, Stomatitis

Symptom Text: I received one (1) shot of the HPV vaccine Gardasil on 09/25/09. Two months later, on 11/19/09, I went into my doctor with petechiae (red blood dots) on my legs, excessive bruising on my legs and arms, and mouth lumps (inside lower lip). I took a blood lab and when the results came in, I was at 8,000 platelet count and told to go to the ER right away. Treatment (steroids alone) lasted for 2 days, and had to go back to the ER, this time with arm numbness/temporary paralysis added to the issue. Treatment with a stronger medication (Anti-D) was administered, but again, two days later, I was back in the ER. A third treatment was administered (IVIG), and it lasted two weeks. Now I am scheduled to go back to the hospital for admission to do another dose of this. Aside from pain at the injection site for over a month, I have also now been diagnosed with the autoimmune disease thrombocytopenia (low blood platelets) which I have been dealing with for over a month at an aggressive level, and it shows no signs of getting better. During this condition, I have had arm numbness/temporary muscle paralysis, as well. 12/23/09 PCP medical records received. Service dates 11/19/09 to 12/21/09. Includes ED visit 11/21/09. Assessment: Idiopathic Thrombocytic Purpura. Patient c/o feeling warm, fatigue. Cough, congestion. Oral contraceptive use. Hematochezia. Paresthesia. Bruising on forearms. Presents at ED with petechiae. Multiple bruises thighs and feet. Bright red blood from nose. Tired. Diarrhea. Bumps in lower lip. Thrombocytopenia. 12/28/09 Discharge summary, hospital records received. Inpatient Service dates 12/8/09 to 12/11/09. Includes Labs from 11/23/09 to 12/22/09. Assessment: Thombocytopenia, Idiopathic Thrombocytopenic Purpura. Prior hospital admissions 11/19/09 to 11/23/09 for Thrombocytopenia / Idiopathic Thrombocytopenic Purpura. 12/2/09 to 12/3/09 for Thrombocytopenia, weakness, heaviness. Patient presented after follow up labs showed a platelet count of 20. (R) arm subjective weakness, headache, nose

Other Meds: Trivora Birth control (oral pill taken 1x per day) Albuterol inhaler (taken as needed for seasonal and pet allergies)

Lab Data: Thrombocytopenia. I have been now been admitted into the hospital 3 times, and have to go back again in a few days, as I have dropped again. My levels have been at 8,000, 3,000, and 12,000 (normal levels are 150,000 - 450,000) at the time

History: No. 12/28/09 Discharge summary, hospital records received. Service dates 11/23/09 to 12/22/09. Asthma. Allergies to erythromycin, penicillin.

Prex Illness: No

Prex Vax Illns:

Vaers Id: **374855-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-Dec-2009	15-Dec-2009	0	23-Dec-2009	23-Dec-2009	CA		23-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0968Y	0	Left arm	Intramuscular	
	FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	102127P1	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncopal episode post approx 10 min post injections (H1N1 and Gardasil)

Other Meds: Orthotricyclen Lo

Lab Data:

History: Seasonal Allergies

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **374878-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Dec-2009	22-Dec-2009	1	23-Dec-2009	23-Dec-2009	CA		15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	0	Left arm	Intramuscular	FLU FLU(H1N1)

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Abdominal tenderness, Flat affect, Hypomagnesaemia, Hypotension, Immunisation reaction, Pyrexia, Tachycardia, Tremor, Viral infection, Vomiting

Symptom Text: pt had fever, vomiting. ```12/28/09 PCP and hospital records DOS 12/22-23/09rec'd. Pt seen for WCC on 12/21/09 and rec'd Gardasil#1. Presented to ER the following day 12/22/09 with c/o stomach pain and vomiting which had resolved somewhat by time of admission. T=103' F. PE (+) for tremulousness/tremor mainly in hands, depressed affect, tachycardia,epigastric tenderness. Given abx and Tamilflu. Renal consult with Impression: Emesis and Fever resolved. (reaction to immunization vs viral). DX: S/P deceased donor renal transplant 8/5/09. Hx of ESRD 2' diarrhea associated hemolytic uremic syndrome. Hypotension. Hypomagnesemia.

Other Meds: prednisone, atenolol, septra, cellcept, zantac, valcyte, norgestimate estradiol, prograf

Lab Data: ```Labs and diagnostics: WBC 5.3. Plt 107. Mg++ 1.4 . Flu (-). UA (+) for 1+ protein, many bacteria. UC (+) for mixed gram (+) flora. CRP 1.0. CO2 24 (L). BC (-).

History: pt is post kidney transplant due to renal failure. ```PMH: Renal transplant 2' to ESRD 2' Hemolytic Uremic Syndrome. Dysfunctional uterine bleeding. Food poisoning age 7. NKA. sister with fever and vomiting also. On OCs.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **374880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Jul-2009	12-Aug-2009	14	23-Dec-2009	23-Dec-2009	CO	Gardasil	22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Menstrual disorder, Muscle spasms, Oestrogen deficiency, Vaginal haemorrhage

Symptom Text: Loss of Period. I have not had a period since I received the vaccine 5 months ago. ```12/30/09 MR received from 6/09 to 11/09. HPV vax given 7/29/09 and 10/21/09. Pt reports no menses since 1st shot. (+) cramps. Occasional spotting. Sent for homone testing and started on Provera for low estrogen.

Other Meds: Loseterin 24

Lab Data: no Lab can determine what is wrong ```Labs and Diagnostics: TSH 1.57, LH/FSH low, Estradiol 20.

History: Gluten Allergy ```PMH: ASCUS, (+) high risk HPV. (+) HSVI&II

Prex Illness: no

Prex Vax Illns: Loss of Period~HPV (Gardasil)~1~25.58~Patient

Vaers Id: **374924-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-Feb-2009	15-Feb-2009	0	23-Dec-2009	24-Dec-2009	FR	WAES0903USA03325	24-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Case of pregnancy follow-up received from a specialist through the Sanofi Pasteur MSD GARDASIL Pregnancy Registry on 11-MAR-2009. A 19 year old female patient with diabetes treated with insulin injection, received the first dose of GARDASIL (batch number not reported) on 15-FEB-2009 while she was pregnant. Her estimated date of last menstrual period was on 12-JAN-2009 and the estimated time of conception was 26-JAN-2009. At time of reporting the patient had no adverse effect. Echography performed on 03-MAR-2009, revealed a uterine sac of 25 mm with cardiac activity. The patient desired to go on with the vaccination. She had no previous pregnancy. There was no familial history of diabetes. Follow up information received by telephone on 14-DEC-2009: Case upgrade to serious upon the basis of the following information: The patient gave birth on 16-SEP-2009 a baby girl by cesarean delivery. The baby weighed 3.840 Kg and was in good health. There was no problem during the pregnancy. The patient was primipara and had no spontaneous abortion. Other business partner numbers included: E2009-02115. No further information is available.

Other Meds: Insulin

Lab Data: Ultrasound, 03Mar09, uterine sac of 25mm with cardiac activity

History:

Prex Illness: Pregnancy NOS (LMP = 12Jan09); Diabetes

Prex Vax Illns:

Vaers Id: **374928-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	11-May-2009	17-Sep-2009	129	23-Dec-2009	28-Dec-2009	TN	WAES0910USA00171B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Right arm	Intramuscular	
	HEPA	UNKNOWN MANUFACTURER	0932X		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Amenorrhoea, Breast tenderness, Dizziness, Drug exposure during pregnancy, Fatigue, Foetal disorder, Headache, Herpes simplex serology positive, Nausea, Papilloma viral infection, Pollakiuria, Pregnancy test positive, Rash erythematous, Rash generalised, Rash pruritic, Smear cervix abnormal, Vaginal discharge

Symptom Text: Information has been received from a registered nurse, a Licensed Practical Nurse (LPN) and medical records for the Pregnancy Registry for GARDASIL, concerning a 17 year old female, gravida 1 Para 0, had chicken pox in the past, with no known drug allergies and with a history of depressive disorder of bipolar for which she was being treated with LEXAPRO (start date not reported) who on 17-AUG-2007 and 11-MAY-2009 was vaccinated with first dose (lot number 656051/0244U) and second dose (659184/0843X), respectively of GARDASIL, both doses were vaccinated in right deltoid IM. On 11-MAY-2009, the patient was also vaccinated with hepatitis A virus vaccine inactivated (MSD) (659832/0932) in left deltoid IM. Concomitant therapy included LEXAPRO and prenatal vitamin oral tablet 27-0.8mg, 1 tablet daily. On an unspecified date after the patient received the second dose of HPV vaccine, a PAP test was positive for HPV. On 16-SEP-2009, the patient presented with amenorrhea and positive home pregnancy test. The patient's LMP was on 01-JUN-2009 and the EDD was 08-MAR-2010. The father of baby (FOB). The patient had a paternal cousin with autism. FOB had a maternal uncle who was born with a diaphragm disorder and the "heart on the wrong side", the description was most suspicious for a congenital diaphragmatic hernia. It was also reported that the FOB's maternal great uncle had Down syndrome and with mental retardation. The patient's grandmother had breast cancer and her grandfather had diabetes and heart disease. After the patient discovered she was pregnant, she stopped taking LEXAPRO (stop date not reported). The patient had a body rash during her first trimester (no further details were provided). On 16-SEP-2009, her EGA was 15 weeks 2 days. Her cycles were regular and occurred approximately every 28 days. Her last pap smear, which was performed in 2007, showed normal, A urine pregnancy test was positive 3 weeks ago, which was on approximately 26-AUG-2009. Her last menstrual period was normal and lasted for 6 days. Since her

Other Meds: LEXAPRO; Vitamins (unspecified)

Lab Data: Ultrasound, 09/16/09, suspected CNS abnormality of fetus and suspected fetal condition; Ultrasound, 09/17/09, fetus has misshapen skull with anterior and posterior bulging at the forehead; Ultrasound 10/08/2009, the right orbit did not ap

History: Chickenpox

Prex Illness: Bipolar disorder; Depressive disorder; Smoker

Prex Vax Illns:

Vaers Id: 374930-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Jan-2009	05-Feb-2009	7	23-Dec-2009	24-Dec-2009	FR	WAES0912USA02186	28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1400U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Hypoaesthesia, Inflammation, Multiple sclerosis, Paraesthesia

Symptom Text: Information has been received from a health professional on 14-DEC-2009 concerning a 16 year old female patient with a history of migraine with aura who on 29-JAN-2009 was vaccinated intramuscularly with the first dose of GARDASIL (lot# 1400U, batch# NH38400) into the upper arm. Concomitant therapy included acetaminophen. On 05-Feb-2009 the patient experienced abdominal feeling of numbness (from TH9 to TH12) and both thighs, first just ventral, then also dorsal. The same day the patient was admitted to hospital. Neurological examination revealed a questionable pyramidal sign right, paraesthesia in both thighs (left > right) and left-sided paraesthesia of the body from TH 9 to TH 12. On 06-FEB-2009 MRI of cervical and thoracic spine showed no indication for inflammatory lesions. Cranial MRI showed suspicious lesions frontal right and in the left pons. VEP (visual evoked potentials) and SEP of tibial nerves (somatosensory evoked potentials) were normal. SEP of medial nerves showed reduced amplitudes on the left side and raised the question of an axonal lesion. CSF showed leucocytes 44/3 cells, protein 342 mg/l, albumin 195 mg/l, (albumin in the serum 39.3 g/l), IgG 43.1 mg/l, (IgG in the serum 9.5g/l), glucose 58 mg/dl, (glucose in the serum 98 mg/dl), lactate in CSF 1.24 mmol/l, oligoclonal bands in CSF detectable, intrathecal IgG-synthesis In Reiber-scheme IgG synthesis without barriers functional disorder. Normal values for: VZV (varicella zoster virus), HSV (herpes simplex virus), FSME (spring-summer encephalitis). Lab findings were normal for electrolytes, CK, transaminases, blood count, coagulation parameters, CRP, TSH, ANA<1:20, folic acid and vitamin B12 level were normal. Anti-HCV and anti-HIV were negative. The hospital physicians assumed a clinical isolated syndrome or a paravaccinal myelitis as adverse event after GARDASIL. The patient was treated with cortisone stosstherapy and subsequent oral tapering. Two days after discharge (12-FEB-2009) the symptoms resolved. During the further course the patien

Other Meds: acetaminophen

Lab Data: magnetic resonance imaging, 06Feb09, MRI of cervical and thoracic spine showed no indication for inflammatory lesions; magnetic resonance imaging, 06Feb09, Cranial MRI showed suspicious lesions frontal right and in the left pons; visual evo

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **374960-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	14-Jul-2008	14-Jul-2008	0	24-Dec-2009	28-Dec-2009	CA	WAES0901USA00343	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood test, Caesarean section, Cholecystectomy, Cholelithiasis, Drug exposure during pregnancy, Streptococcal identification test negative

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL, concerning a 27 year old female with PENICILLIN allergy and no other medical history who was intramuscularly vaccinated with the first and second 0.5 ml doses of GARDASIL on 14-July-2008 and 15-Sep-2008 (1st lot #660557/0072X) 2nd lot #659184/0843X), respectively. Concomitant therapy included diphtheria toxoid/tetanus toxoid which was vaccinated with the first dose of GARDASIL. Subsequently the patient became pregnant after receiving GARDASIL. The due date of pregnant gestation reported as 13-May-2009. No adverse effect reported. Laboratory diagnostic studies included prenatal blood tests. The patient sought unspecified medical attention. Follow up information was received from the registered nurse who reported that the patient had a history of irregular periods and she had reported that she was not pregnant at the time of her vaccination with GARDASIL in September 2008. The reporter administered the vaccine to the patient and estimated that the patient was approximately 5 weeks pregnant at the time of vaccination. On 30-Apr-2009 this patient delivered her baby by c-section following spontaneous rupture of membranes. Amniotic fluids were clear. Patient was GBS negative. Gestational age was 38 weeks +. It was also reported that the patient experienced cholelithiasis during pregnancy on 23-Mar-2009 and underwent a cholecystectomy on 27-May-2009. Upon internal review, c-section following spontaneous rupture of membranes was considered to be an other important medical event. The baby's experience has been captured WAES # 0901USA00343B1. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Irregular periods

Prex Illness: Pregnancy NOS (LMP - 08/06/2008) PENICILLIN allergy

Prex Vax Illns:

Vaers Id: **374963-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-May-2007	10-Jul-2009	788	24-Dec-2009	24-Dec-2009	WI		10-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1447F	1	Right arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Alopecia, Arthralgia, Asthenia, Bladder spasm, Dysuria, Joint swelling, Micturition urgency, Musculoskeletal pain, Synovitis

Symptom Text: Pain in shoulders mostly and other joints, knees, feet, elbows, jaw. ``` MR received 12/28/09, 12/31/09, and 1/5/10 for dates 7/10/07 to 12/8/09. DX: rheumatoid arthritis. CC: pt states a few weeks after second HPV vax had c/o joint pain around left knee in 2007, later in 2008 c/o rt shoulder pain lasting 2-3 days. Later sx disappeared. Pt states 2/09 multiple joint pain occurred and worsened. At time of this appt pt c/o TMJ pain, bilat shoulder pain, swelling in elbows, wrists, and hands. Pt expressed an increase in thirst. Pt has h/o bulls eye rash which she was treated for. Assessment: multiple joint synovitis (+). Additional OV pertaining to f/u of RA. Some improvement noted but symptoms persist. Pt experiencing alopecia due to medication. PT 12/15/09 for generalized weakness. OV 12/16/08 DX: bladder spasms. CC: difficulty urinating/urgency. Pt denies sexual activity, UA(-). Assessment WNL.

Other Meds:

Lab Data: RA factor found in blood tests, positive for Rheumatoid Arthritis ``` MR received 12/28/09, 12/31/09, and 1/5/10 Diag/labs: ANA(+), xray(-), MRI(-).

History: No ``` MR received 12/28/09, 12/31/09, and 1/5/10 PMH: h/o seropositive rheumatoid arthritis, tinea versicolor, vaginal yeast infection 12/07

Prex Illness: No

Prex Vax Illns:

Vaers Id: **374964-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.7	M	14-Jul-2008	06-Aug-2008	23	24-Dec-2009	28-Dec-2009	--	WAES0901USA00343B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bronchoscopy, Congenital myopathy, Hypotonia, Intensive care, Laryngomalacia, Mechanical ventilation, Pneumonia, Pneumonia aspiration, Respiratory disorder neonatal, Respiratory failure

Symptom Text: Information has been received from a registered nurse concerning a male baby whose mother was vaccinated with two doses of GARDASIL on 14-JUL-2008 and 15-SEP-2008 and was pregnant. On 30-APR-2009, the infant was born with problems. He had no respiratory effort at birth and required mechanical ventilation at a couple hours of life. The infant was admitted to a neonatal intensive care unit (NICU), then was transferred to another neonatal intensive care unit (NICU) and again transferred to another neonatal intensive care unit (NICU) for additional work-up on 05-MAY-2009, a pulmonologist performed a flexible bronchoscopy on the baby which showed mild laryngomalacia with normal vocal cord function. On 31-JUL-2009, the infant had suspected pneumonia, respiratory syncytial virus (RSV) was negative, influenza was negative. Respiratory cultures were positive for Ecoli. The infant alternated between being stable on room air and requiring respiratory assistant by bi-pap or nasal cannula through August 2009, remaining in the neonatal intensive care unit. In September 2009, the baby had suspected aspiration pneumonia with migrating infiltrates on chest x-ray. The baby was ultimately diagnosed with low respiratory muscle tone, respiratory failure and congenital myopathy. The baby had been referred to a children services at this time. The mother's experienced has been captured in WAES #0901USA00343. Additional information has been requested.

Other Meds: Unknown

Lab Data: bronchoscopy, 05/28/09, mild laryngomalacia with normal vocal cord function; diagnostic laboratory, 07/31/09, influenza was negative; chest X-ray, 09/??/09, migrating infiltrates; nasopharyngeal RSV, 07/31/09, negative; upper respiratory, 0

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **374965-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Dec-2009	09-Dec-2009	0	24-Dec-2009	28-Dec-2009	NY	WAES0909USA01213	28-Dec-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	UF460CA	1	Unknown	Unknown	
VARCEL	MERCK & CO. INC.	1086Y	1	Unknown	Unknown	
HPV4	MERCK & CO. INC.	1318Y	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, Syncope

Symptom Text: Information has been received from a physician concerning a patient who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine (lot#, route and site of administration not reported). Subsequently, the patient has a syncopal episode. At the time of this report, the patient's outcome was unknown. Follow up information has been received from a physician concerning a 16 year old female patient with no other relevant medical histories who on 09-DEC-2009, at 11:30, was vaccinated with the second dose of GARDASIL vaccine (lot#665547/1318Y) into the left arm, a second dose of VARIVAX vaccine (Oka/Merck) (lot# 665040/1086Y) into the right arm and a second dose of ADACEL (lot# UF460CA) into the right arm. On 09-DEC-2009 the patient developed syncope and a brief tonic clonic seizure that lasted 5-10 seconds. The patient was having her annual physical examination at time of vaccination. No medical attention was sought. There were no laboratory diagnostics studies performed. On 09-DEC-2009 the patient recovered. Upon internal review, tonic clonic seizure was considered to be an other important medical event. This is one of several reports from the same source. Additional information is not expected.

Other Meds:

Lab Data: none

History: none

Prex Illness: Physical examination

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **374984-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Dec-2009	25-Dec-2009	24	25-Dec-2009	28-Dec-2009	VA		28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed, Pregnancy test negative

Symptom Text: Menstrual bleeding(period) has been delayed for 15 days. No bleeding as of this day. Pregnancy blood test is negative.

Other Meds: None

Lab Data: None

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **374988-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	22-Dec-2009	22-Dec-2009	0	26-Dec-2009	28-Dec-2009	CA	Gardasil Vaccine	28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysmenorrhoea

Symptom Text: Soon after receiving the Gardasil Vaccine I began experiencing menstrual cramps. They were sporadic and light the first day. By 12/25/09 they had gotten much worse and I began my period. My menstrual cycle is very regular and occurs in the first week of every month.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **374996-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Aug-2009	17-Aug-2009	0	26-Dec-2009	28-Dec-2009	CA		28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL	5	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Syncope

Symptom Text: After first Gardasil vaccine, my daughter became pale, dizzy, and fainted while trying to walk. Had to be carried by nurse and myself (Mom) and returned to exam room to lie down.

Other Meds: None

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375016-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	14-Dec-2009	14-Dec-2009	0	27-Dec-2009	28-Dec-2009	FL		03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Right arm	Intramuscular	FLU FLU(H1N1)

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Dizziness, Headache, Hypoaesthesia, Insomnia, Nausea, Neuropathy peripheral, Paraesthesia, Visual impairment, Vomiting

Symptom Text: I received the Guardasil shot series over the course of 6 months. After the first shot given in May, I was nauseous and vomited. I also developed severe facial acne that I'm still experiencing, two weeks after the first shot. I don't remember any problems after the second shot in August. Severe symptoms started on the evening the third shot was administered December 14, 2009. I had constant tingling in my right limbs (arm, all the way down to the tips of my fingers, and leg, from the knee down to the foot): the shot was given in my right arm. I was still able to walk and use my arm. It was not a sharp pain, just constant. By Thursday, Dec. 17 at 4 A.M., the tingling was prevalent in all my limbs and my feet felt numb. I went to the emergency room on Thursday, Dec. 17, 3 days after the shot as the tingling was worse and not subsiding. They ran a CT scan to rule out shunt problems since I have a VP shunt. All was fine with the shunt. On Friday Dec. 18, I went to another emergency room so I could be evaluated by a neurologist. He ran reflex tests and everything was working well. He diagnosed neuropathy and said he thought it would eventually subside. That night I experienced swimming vision for a few minutes and a headache. I had trouble sleeping each night, unable to get comfortable in bed; the tingling seemed to be worse when lying down. The next day I felt dizzy, had an intermittent headache, and experienced vision problems if there were bright lights. By Sunday, the symptoms became less severe and over the course of the next week, diminished completely. ```MR received 11/29/09, 11/30/09 and 12/28/09 for DOS 12/17/09 and 12/18/09. DX: Neuropathy. Pt c/o tingling in R side extremities for 3 days. Neuro exam wnl. Pt to follow up with neurologist. Pt discharged home. Pt was seen by a neurologist the next day and cleared of GBS. Impression: subjective numbness of L extremities and R U E. Pt seen on 12/28/09 and tingling had resolved.

Other Meds:

Lab Data: I had also received the H1N1 vaccination as well as the flu shot, about a month a before taking this final Guardasil shot. ```Lab and DX studies: Pain 6/10, CT wnl.

History: Codine, Hydrocephalus, VP Shunt ```PMH: hydrocephalus, ventriculoperitoneal shunt. Allergies: Codeine.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **375032-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Dec-2009	28-Dec-2009	FR	WAES0912USA02323	28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Central nervous system inflammation, Multiple sclerosis

Symptom Text: Information was reported in a newspaper article via media monitors and CSL concerning a female patient (age was reported as a teenager to a woman in her early 20's) who could have been predisposed to multiple sclerosis (MS) or who had a prior history of symptoms was vaccinated with a dose of GARDASIL. Within three weeks of vaccination the patient experienced multiple sclerosis symptoms. The symptoms lasted from weeks to months. The patient had recovered. It was reported that GARDASIL may have triggered multiple sclerosis (MS) symptoms in some girls, who later recovered. A neurologist reported that five cases were reported in a journal article in January. Another five have since emerged. The neurologist stated GARDASIL was not the cause of MS; whether or not it was a trigger for episodes for inflammation in the brain in these rare cases is unclear. All cases were aged under 26. Symptoms began within three weeks of vaccination and lasted from weeks to months. The physician stressed that all those affected had recovered. Attempts are being made to obtain additional identifying information to distinguish the individual patients in the newspaper article. Additional information will be provided if available. No further information is available. The article also discussed the experience of other 9 patients while on therapy with GARDASIL (WAES 0912USA01664, WAES 0912USA02322, WAES 0912USA02324 and WAES 0912USA02325, WAES 0711AUS00143, WAES 0807AUS00041, WAES 0807AUS00274, WAES 0807AUS00280, WAES 0807AUS00277 and the auto-immune symptoms of a 14 year old on therapy with GARDASIL (WAES 0912USA02326).

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **375033-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Dec-2009	28-Dec-2009	FR	WAES0912USA02324	28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information was reported in a newspaper article via media monitors and CSL concerning a female patient (age was reported as a teenager to a woman in her early 20's) who could have been predisposed to multiple sclerosis or who had a prior history of symptoms was vaccinated with a dose of GARDASIL. Within three weeks of vaccination the patient experienced multiple sclerosis symptoms. The symptoms lasted from weeks to months. The patient had recovered. It was reported that GARDASIL may have triggered multiple sclerosis symptoms in some girls, who later recovered. A neurologist reported that five cases were reported in a journal article in January. Another five have since emerged. The neurologist stated GARDASIL was not the cause of MS; whether or not it was a trigger for episodes of inflammation in the brain in these rare cases is unclear. All cases were aged under 26. Symptoms began within three weeks of vaccination and lasted from weeks to months. The physician stressed that all those affected had recovered. Attempts are being made to obtain additional identifying information to distinguish the individual patients in the newspaper article. Additional information will be provided if available. No further information is available. The article also discussed the experience of other 9 patients while on therapy with GARDASIL (WAES 0912USA01664, WAES 0912USA02322, WAES 0912USA02322, WAES 0912USA02323 and WAES 0912USA02325, WAES 0711AUS00143, WAES 0807AUS00041, WAES 0807AUS00274, WAES 0807AUS00280, WAES 0807AUS00277 and the auto-immune symptoms of a 14 year old on therapy with GARDASIL (WAES 0912USA02326).

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **375034-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Dec-2009	28-Dec-2009	FR	WAES0912USA02325	28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information was reported in a newspaper article via media monitors and CSL concerning a female patient (age was reported as a teenager to a woman in her early 20's) who could have been predisposed to multiple sclerosis (MS) or who had a prior history of symptoms was vaccinated with a dose of GARDASIL. Within three weeks of vaccination the patient experienced multiple sclerosis symptoms. The symptoms lasted from weeks to months. The patient had recovered. It was reported that GARDASIL may have triggered multiple sclerosis (MS) symptoms in some girls, who later recovered. A neurologist reported that five cases were reported in a journal article in January. Another five have since emerged. The neurologist stated GARDASIL was not the cause of MS; whether or not it was a trigger for episodes of inflammation in the brain in these rare cases is unclear. All cases were aged under 26. Symptoms began within three weeks of vaccination and lasted from weeks to months. The physician stressed that all those affected had recovered. Attempts are being made to obtain additional identifying information to distinguish the individual patients in the newspaper article. Additional information will be provided if available. No further information is available. The article also discussed the experienced of other 9 patients while on therapy with GARDASIL (WAES 0912USA01664, WAES 0912USA02322, WAES 0912USA02322 and WAES 0912USA02324, WAES 0711AUS00143, WAES 0807AUS00041, WAES 0807AUS00274, WAES 0807AUS00280, WAES 0807AUS00277 and the auto-immune symptoms of a 14 year old on therapy with GARDASIL (WAES 0912USA02326).

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375035-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Dec-2009	28-Dec-2009	FR	WAES0912USA01664	28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information was reported in a newspaper article via media monitors and CSL concerning a female patient (age was reported as a teenager to a woman in her early 20's) who could have been predisposed to multiple sclerosis or who had a prior history of symptoms was vaccinated with a dose of GARDASIL. Within three weeks of vaccination the patient experienced multiple sclerosis symptoms. The symptoms lasted from weeks to months. The patient had recovered. It was reported that GARDASIL may have triggered multiple sclerosis symptoms in some girls, who later recovered. A neurologist reported that five cases were reported in a journal article in JANUARY. Another five have since emerged. The neurologist stated GARDASIL was not the cause of MS: whether or not it was a trigger for episodes of inflammation in the brain in these rare cases is unclear. All cases were aged under 26. Symptoms began within three weeks of vaccination and lasted from weeks to months. The physician stressed that all those affected had recovered. Attempts are being made to obtain additional information to distinguish the individual patients in the newspaper article. Additional information will be provided if available. No further information is available. The article also discussed the experience of other 9 patients while on therapy with GARDASIL (WAES 0912USA02323, WAES0912USA02324 and WAES 0912USA02325, WAES 0711AUS00143, WAES 0807AUS00041, WAES0807AUS00274, WAES0807AUS00280, WAES 0807AUS00277 and the auto-immune symptoms of a 14 year old on therapy with GARDASIL (WAES0912USA02326).

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **375036-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-May-2007	11-Jul-2007	50	24-Dec-2009	28-Dec-2009	FR	WAES0912USA02946	28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0859F	0	Unknown	Intramuscular	

Seriousness: DIED, HOSPITALIZED, SERIOUS

MedDRA PT Autopsy, Death, Osteitis

Symptom Text: Information has been received from a physician concerning a previous healthy 17 year old female patient with no relevant medical history who on 22-MAY was vaccinated intramuscularly with her first dose of GARDASIL (Lot # 654740/0859F) (Batch # NE29660) (Injection site was not reported). Concomitant therapy included VALETTE. On 11-JUL-2007 the reporter was informed by the patient's mother that her daughter was hospitalized due to bone inflammation. On 15-JUL-2007, approximately 7 weeks post vaccination, the patient died of unknown cause. An autopsy was carried out, but the result was not known to the reporter up to the time of reporting. A lot check has been initiated. Other business partner numbers include E2009-11667. Additional information has been requested.

Other Meds: VALETTE

Lab Data: Unknown

History: none

Prex Illness:

Prex Vax Illns:

Vaers Id: **375037-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Dec-2009	28-Dec-2009	FR	WAES0912USA02322	28-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information was reported in a newspaper article via media monitors and CSL concerning a female patient (age was reported as a teenager to a woman in her early 20's) who could have been predisposed to multiple sclerosis (MS) or who had a prior history of symptoms was vaccinated with a dose of GARDASIL. Within three weeks of vaccination the patient experienced multiple sclerosis symptoms. The symptoms lasted from weeks to months. The patient had recovered. It was reported that GARDASIL may have triggered multiple sclerosis (MS) symptoms in some girls, who later recovered. A neurologist reported that five cases were reported in a journal article in January. Another five have since emerged. The neurologist stated GARDASIL was not the cause of MS; whether or not it was a trigger for episodes of inflammation in the brain in these rare cases is unclear. All cases were aged under 26. Symptoms began within three weeks of vaccination and lasted from weeks to months. The physician stressed that all those affected had recovered. Attempts are being made to obtain additional identifying information to distinguish the individual patients in the newspaper article. Additional information will be provided if available. No further information is available. The article also discussed the experienced of other 9 patients while on therapy with GARDASIL (WAES 0912USA01664, WAES 0912USA02323, WAES 0912USA02324 and WAES 0912USA02325, WAES 0711AUS00143, WAES 0807AUS00041, WAES 0807AUS00274, WAES 0807AUS00280, WAES 0807AUS00277 and the auto-immune symptoms of a 14 year old on therapy with GARDASIL (WAES 0912USA02326).

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 375038-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	12-Dec-2008	05-Jan-2009	24	24-Dec-2009	28-Dec-2009	AZ	WAES0912USA02098	27-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Chest discomfort, Chest pain, Dehydration, Dizziness, Echocardiogram, Malaise, Palpitations, Presyncope, Sinus congestion, Sinus tachycardia, Tachycardia, Viral infection

Symptom Text: Information has been received from a physician concerning a 24 year old female patient with no known drug allergies or pertinent medical history who on 12-DEC-2008 was vaccinated with the first dose of GARDASIL (Lot number 661764/0650X). Concomitant therapy included birth control pills. The patient developed SBT (Supra Ventricular Tachycardia) and she was hospitalized. The patient could not remember the exact date of her hospital confinement when she reported the event to the physician she thought it to be two weeks after the vaccination. The patient told her physician she underwent an electrocardiogram (EKG), echocardiogram (ECHO) and exam with no results provided to the reporting physician. No surgery was performed. On an unspecified date the patient was discharged from cardiologist's care. The patient will not receive further doses of GARDASIL as the patient believed the event was caused by the vaccine. The physician reported that there was no association between SVT and GARDASIL. At the time of the report the patient had recovered. "Supra Ventricular Tachycardia" was considered by the physician to be life-threatening. No further information is available. ```12/30/2009 ER records rec'd for DOS 1/5/2009 with dx: Presyncope. Chest pain. Pt presented to the ER after an episode of heart paplitations, tachycardia, dizziness and chest tightness. Pt in sinus tach at 143 which reduced to 102 after IVF bolus. Mildly dehydrated. Also c/o feeling unwell, and sinus-infection type sx. MD suspects sx r/t viral syndrome.

Other Meds: hormonal contraceptives

Lab Data: Unknown ```Labs and Diagnostics: EKG sinus tach. CXR WNL. Na+ 132, Cl- 97. K+ 3.2. Cardiac enzymes (-). CT brain (-). Chest CT (+) for mild basilar atelectasis. WBC 16.6 with 15 bands.

History: Unknown ```PMH: none. on OCs

Prex Illness:

Prex Vax Illns:

Vaers Id: **375163-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-May-2009	12-May-2009	0	28-Dec-2009	29-Dec-2009	ME	GARDASIL	29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	VACCINATION Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Abdominal pain upper, Back pain, Dizziness, Eye pain, Nausea, Syncope

Symptom Text: FAINTED, DIZZY AFTER COMING TO, SICK TO HER STOMACH, STOMACH HURTING, THAT NIGHT VERY DIZZY, STOMACH PAIN, BACK PAIN, EYE PAIN. THIS ALL CONTINUES

Other Meds:

Lab Data:

History: ALLERGIC TO CECLOR

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375170-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Dec-2009	28-Dec-2009	0	28-Dec-2009	29-Dec-2009	PA		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold compress therapy, Dizziness, Dyskinesia, Eye rolling, Feeling abnormal, Hyperhidrosis, Hypotension, Loss of consciousness, Muscle twitching, Posture abnormal

Symptom Text: My daughter was told by a nurse to sit for 2-3 minutes after the injection of Gardasil. My daughter did this, slowly stood upright to make sure she felt alright after 3 minutes. She felt fine, stood by exam table for another 2 minutes and then we proceeded to check out at desk. We headed for the exit door of the pediatricians office, my daughter stopped walking, said she didn't feel right, felt very dizzy, her eyes rolled up into the back of her head several times, her head was wobbling (like she couldn't support it), her legs were like rubberbands and she started collapsing in my boyfriends arms. He layed her down on the office floor. My daughter was completely passed out, sweating, and her legs and arms were jerking and twitching like she was having a seizure!! I immediately got the nurse who administered the shot, and they took her blood pressure and said it was very low and I asked for cold compresses for her head. This all happened within 10-15 minutes after the vaccination of Gardasil!!

Other Meds: Microgestin FE Tabs 28

Lab Data:

History: No pre-existing medical conditions.

Prex Illness: No Illness at time of vaccination. Healthy teenage girl.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375191-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Dec-2009	10-Dec-2009	1	29-Dec-2009	29-Dec-2009	PA		29-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Urticaria over upper ext, back, neck, face 2 days after receiving GARDASIL #3.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **375193-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Dec-2009	28-Dec-2009	0	29-Dec-2009	29-Dec-2009	PA		13-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pain, Paraesthesia oral, Swollen tongue

Symptom Text: Patient c/o tongue feeling weird after shot c/o nausea 1/2-10 after shot. Also c/o body aches rest of day. About 7 hrs after she received the shot, she had tongue swelling. Parents gave BENADRYL & swelling resolved. No resp distress/no difficulty swallowing.

Other Meds: YAZ

Lab Data:

History: Fatigue; Depression

Prex Illness:

Prex Vax Illns:

Vaers Id: 375357-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Dec-2008	05-Dec-2008	0	29-Dec-2009	30-Dec-2009	PA	WAES0902USA02182	30-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anal abscess, Chorioamnionitis, Drug exposure during pregnancy, Fungal infection, Funisitis, Infection, Labour complication, Vasculitis

Symptom Text: Information has been received from a nurse for the Pregnancy Registry for GARDASIL concerning a 21 year old female with no medical history or drug allergy who on 05-DEC-2008 was vaccinated with the second dose of GARDASIL (0947X). There was no concomitant medication. The patient's LMP was on 14-NOV-2008 and then the patient came into the clinic to receive the second dose of GARDASIL. Before the second dose of GARDASIL the patient was given a pregnancy test which came back negative and therefore the patient was given the second dose of GARDASIL. The patient came back into the clinic on 29-JAN 2009 and the patient found out she was pregnant. The nurse reported that the patient was approximately about a week to three weeks pregnant at the time she received the second dose of GARDASIL on 05-DEC-2008. No AE involved. The patient performed urine pregnancy test. The patient sought medical attention. Follow up information has been received from a registered nurse, concerning the patient with no illness at the time of vaccination or no pre-existing allergies or birth defects on 13-AUG-2008 received the first dose of GARDASIL and on 05-DEC-2008 AM received the second dose of GARDASIL IM on deltoid. The patient with 5 previous pregnancies had 1 full term delivery at 42 weeks from LMP, no pre-term delivery, 1 spontaneous abortions at 16 weeks from LMP, 3 elective terminations at unknown weeks from LMP and no fetal death. There was no birth defects in previous pregnancies. It was unknown if there any infant complications in previous pregnancies. Concomitant therapy included vitamins (unspecified). On 05-DEC-2008 the patient did a colposcopy pasts due for the second dose of GARDASIL. On 05-DEC-2008 pregnancy test was negative - specific gravity of urine was 1.025. The patient returned to office on 29-JAN-2009 and pregnancy test positive. On 23-MAR-2009 the patient did ultrasound for fetal structure scan and results indicated no abnormal findings. On 02-JUL-2009 the patient was treated with KEFLEX 500 mg 4 x/day for 7 days for

Other Meds: vitamins (unspecified)

Lab Data: colposcopy, 12/05/09; ultrasound, 03/23/09, fetal structure scan: no abnormal findings; urine beta-human, 01/29/09, pregnant; urine specific gravity, 12/15/09, 1.025; urine beta-human, 12/05/08, negative

History:

Prex Illness: Pregnancy NOS (LMP = 11/14/2008); Routine health maintenance

Prex Vax Illns:

Vaers Id: **375360-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	13-Aug-2008	Unknown		29-Dec-2009	30-Dec-2009	PA	WAES0902USA02182B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Sepsis, Tachypnoea

Symptom Text: Information has been received from a registered nurse concerning a male patient whose mother on 13-AUG-2008 received the first dose of GARDASIL and on 05-DEC-2008 AM received the second dose of GARDASIL IM on deltoid. The patient was delivered on 15-AUG-2009, at 39 weeks from LMP. The patient weight 3628gm, length 51cm, Apgar score 8/9 and head circumference 33. Subsequently the baby developed tachypnea and presumed sepsis and was hospitalized. Course of IV antibiotics for 10 days. The baby was discharged on 25-AUG-2009. At the time of the report the outcome of the patient was unknown. No further information is available. The mother's experience has been captured in WAES0902USA02182.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 375362-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Mar-2008	Unknown		29-Dec-2009	30-Dec-2009	KY	WAES0912USA02352	30-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Epstein-Barr virus infection, Fatigue

Symptom Text: Information has been received from a physician concerning an 18 year old female patient with fatigue, depression and insomnia who was vaccinated with the first, second and third dose of GARDASIL on 06-AUG-2007, 06-NOV-2007 and 04-MAR-2008 respectively. Concomitant therapy included ZOLOFT, SEROQUEL and maybe CORTEF. The physician reported that after the third dose vaccination with GARDASIL, the patient experienced chronic fatigue and EPSTEIN-BARR syndrome. The physician also reported that about two weeks after the vaccination, on approximately 18-MAR-2008, the patient was diagnosed with EPSTEIN-BARR syndrome. Thyroid test(results not provided) and EPSTEIN BARR test were performed. The EPSTEIN-BARR test was positive. The patient sought medical attention in the office. It was reported that the patient was unable to attend her last semester of high school due to fatigue. At the time of the report the patient had not recovered. All telephone attempts to obtain follow-up information have been unsuccessful. The patient's chronic fatigue and EPSTEIN BARR syndrome were considered to be disabling by the physician. Additional information has been requested.

Other Meds: CORTEF; SEROQUEL; ZOLOFT

Lab Data: thyroid function test, 03/??/08, results not provided; EPSTEIN-BARR virus, 03/18?/08, positive

History:

Prex Illness: Depression; Insomnia; Fatigue

Prex Vax Illns:

Vaers Id: **375363-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Dec-2009	30-Dec-2009	--	WAES0912USA02381	30-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Adverse event, Disability, Impaired work ability

Symptom Text: Information has been received from a consumer that read an article "maybe last summer" concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (route and lot # unknown) and she was "messed up". The consumer did not remember what specific adverse effects the patient experienced but the patient could no longer work. At time of this report the patient outcome was unknown. Mess up/adverse event was considered to be disabling. Attempts are being made to verify the existence of an identifiable patient and reporter. Additional information has been requested.

Other Meds: unknown

Lab Data: Unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **375364-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Jan-2009	25-Jan-2009	5	29-Dec-2009	30-Dec-2009	FR	WAES0912USA02996	30-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion

Symptom Text: Information has been received on 16-DEC-2009 from a foreign regulatory authority (ESAGEMED 107125342) concerning a 15 year old female with a history of partial epilepsy with symptomatic control who on 20-JAN-2009 was vaccinated IM with a dose of GARDASIL (lot number not reported). On 25-JAN-2009, 5 days after vaccine administration, the patient experienced a generalised tonic-clonic seizure. The patient recovered on the same day on 25-JAN-2009. A sleep electroencephalography (EEG) was performed before and after RAM phase with normal results. Case reported as serious by the Health Authority with other medically important condition as criteria. Case is closed. Other business partner numbers include: E2009-11679. No further information is available.

Other Meds: Unknown

Lab Data: electroencephalography, sleep EEG before and normal PAM phase with normal results

History: Partial epilepsy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375371-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Dec-2009	18-Dec-2009	0	29-Dec-2009	30-Dec-2009	PA		30-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Injection site pain, Oedema peripheral

Symptom Text: Beginning about 6 to 7 hours after administration developed pain radiating from right arm from injection site, fingers of right hand became swollen. Swelling persisted into 12/22 with decreased strength of hand. Hand returned to normal 12/23 but still pain upper arm at site of injection.

Other Meds: ADDERALL XR

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **375408-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Dec-2009	29-Dec-2009	0	29-Dec-2009	30-Dec-2009	VA		30-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0669Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Dizziness, Heart rate decreased, Hypotension, Loss of consciousness, Nausea, Pallor, Skin discolouration, Stupor

Symptom Text: Patient after having shot felt dizzy and nausea afterwards. She passed out in waiting room. She was brought back and laid down on bed. Blood pressure at that time 55/35 and pulse was 35. She was confused and stuperous. Patients color was very pale but eventually returned to pink after several mins and back to normal color after about 6-7 mins. Blood pressure increased to 88/55 and pulse was up to 70. After 20 mins of patient laying down she was able to sit up and carry on conversations as well as walk without difficulty. This was patients 2nd HPV and advised to not have 3rd HPV due to the reaction.

Other Meds: BenzaClin 1%/5% Topical Gel Flovent 110mcg Oral Inhaler

Lab Data:

History: Asthma and Acne

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375409-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Dec-2009	28-Dec-2009	0	29-Dec-2009	30-Dec-2009	AR		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Chills, Headache, Injection site pain, Nausea, Pain, Pyrexia

Symptom Text: Headache, then chills/fever; bouts of nausea; pain at the sight; joint pain and pain in R side. Symptoms seemed to peak @ 8:00 AM 12/29/2009, with fever slightly in excess of 102. Treated somewhat effectively with ibuprofen.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **375410-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	10-May-2007	01-May-2008	357	29-Dec-2009	30-Dec-2009	CA		27-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	2	Right arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Arthralgia, Arthropathy, Joint swelling, Rheumatoid arthritis, Surgery

Symptom Text: Rheumatoid Arthritis starting in left food then going to the other foot. Can't walk. On medication with predisone, methotrexate. Symptoms started small now pain and severe chronic swelling in ankles. MRI and surgery showed no signs of injury. ```1/8. 1/12, 1/19/2010 Orthopedic consult notes, Rheumatologist records, dx: inflammatory arthropathy, RA patient with c/o's lt ankle swelling and pain, tx'd with steroids, cortisone injections, Sulfasalazine and methotrexate

Other Meds:

Lab Data: inflammation in blood ```1/8. 1/12, 1/19/2010 Orthopedic consult notes, Rheumatologist records, dx: inflammatory arthropathy, RA Labs: CBC, Lyme titer, ANA, RA, all negative, ESR and CRP both high, HLAB27 pending Dx studies: MRI lt ankle

History: Heart murmur ```1/8. 1/12, 1/19/2010 Orthopedic consult notes, Rheumatologist records, dx: inflammatory arthropathy, RA PMH: heart murmur Allergies: NKDA

Prex Illness: no ```1/8. 1/12, 1/19/2010 Orthopedic consult notes, Rheumatologist records, dx: inflammatory arthropathy, RA

Prex Vax Illns:

Vaers Id: **375511-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Dec-2009	01-Dec-2009	0	30-Dec-2009	31-Dec-2009	FR	WAES0912USA02997	31-Dec-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Information has been received on 16-DEC-2009 from the foreign Health Authority (ES AGEMED 921903341) concerning a 14 year old female who on 01-DEC-2009 was vaccinated IM with the first dose of GARDASIL vaccine (batch number and site of administration not reported). On 01-DEC-2009 the patient suffered a syncope (coded as a loss of consciousness by the Health Authority) immediately after vaccine administration. Once the patient recovered consciousness, her vital signs were normal. The patient had physiological serum i.v placed and was transferred to the hospital for observation (it had not been reported that the patient was hospital admitted). The patient was recovered on 01-DEC-2009. Case reported as serious by the Health Authority with other medically important condition as criteria. Case is closed. Other business partner numbers include: E2009-11625. No further information is available.

Other Meds: Unknown

Lab Data: vital sign, normal

History: none

Prex Illness:

Prex Vax Illns:

Vaers Id: **375578-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	30-Dec-2009	31-Dec-2009	1	31-Dec-2009	31-Dec-2009	OH		11-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3100AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1013Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB387BA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	UF500CA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Urticaria

Symptom Text: Mom states Pt woke up around 3am with abdominal pain and covered in hives. Pt went to ER and given SOLU-MEDROL 125mg and Benadryl. Sent home with Rx for prednisone & told to take Benadryl three time today.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **375629-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jul-2009	03-Jul-2009	0	31-Dec-2009	04-Jan-2010	MI	WAES0912USA03117	04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a 16 year old female consumer with no drug reactions/allergies and a history of asthma, for GARDASIL, a Pregnancy Registry product. It was reported that on 03-JUL-2009 the patient was vaccinated with the first dose of series of GARDASIL. There was no concomitant medication. The patient reported that at the end of July 2009 she found out she was pregnant. The consumer reported that on 04-Aug-2009 she had terminated the pregnancy and had recovered. The consumer reported that she had not received any additional doses of GARDASIL. No adverse event was involved. It was reported that therapy with GARDASIL was discontinued and that the patient recovered on an unspecified date while on therapy. Therapy with GARDASIL was not reintroduced. The patient sought unspecified medical attention. No laboratory diagnostics studies were performed. Upon internal review abortion induced was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Asthma

Prex Illness:

Prex Vax Illns:

Vaers Id: 375630-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-Aug-2009	11-Dec-2009	106	31-Dec-2009	04-Jan-2010	FR	WAES0912USA03157	04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1339F	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Muscle spasms

Symptom Text: Information has been received from a gynecologist concerning a 17 year old female patient who on 22-SEP-2008 was vaccinated with the first dose of GARDASIL (lot#1316U, batch# NH45640) and on 27-AUG-2009 was vaccinated with the second dose of GARDASIL (lot#1339F, batch#NF23310) intramuscularly into the upper arm. On 11-DEC-2009 the patient developed uncontrolled muscle cramps and was hospitalized on the same day. The reporter pointed out that "two strong adult men were unable to hold her". At the time of the reporting the patient had not recovered. D1 of GARDASIL, was well tolerated. Other business partner numbers included E2009-11711.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 375631-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		31-Dec-2009	04-Jan-2010	FR	WAES0912USA03160	04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Body temperature fluctuation, Fatigue, Pharyngeal erythema, Pyrexia

Symptom Text: Information has been received from a physician in a foreign country on 16-DEC-2009 concerning a 15 year old female who had received the first dose of GARDASIL in October 2009. The day following vaccination, the patient presented with very high fever and was hospitalised. Several blood and serological work-ups were performed, nothing was found. Fever lasted for more than three weeks. At the time of reporting the evolution was unknown. To be noted that this adopted patient with unknown family medical history often presented with very elevated bout of fever during childhood. Additional information received by telephone on 21-DEC-2009: The patient presented with bout of fever up to 40 degrees C during several days. Fever was irregular: down to 38 degrees C. resolved for one or two days, increasing again. The patient went on a visit to hospital twice before being admitted for a few days. Work-up was negative. Influenza was ruled out. Fever was final diagnosis. The day post vaccination the patient also presented with a red throat that lasted 8 days and fatigue that lasted one month. The patient received a corrective treatment with paracetamol and ORELOX for eight days for pharyngitis. At the time of reporting, the patient had recovered. Other business partner numbers include E2009-11691.

Other Meds: Unknown

Lab Data: body temp, ??Oct09, Up to 40 degrees C down to 38 degrees C. Irregular.; hematology, ??Oct09, Blood and serum work up: nothing was found: Negative

History: Fever

Prex Illness:

Prex Vax Illns:

Vaers Id: 375655-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	16-Dec-2009	16-Dec-2009	0	02-Jan-2010	04-Jan-2010	CA		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Heart rate decreased, Pallor, Vomiting

Symptom Text: pale, felt faint, vomited. Lay down: 82/34 b/p with pulse 48, O2sat 98%, after a few minutes, felt better, stood w/ bp of 97/60, pulse 91, left feeling well per pt

Other Meds:

Lab Data: none

History: NONE

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375660-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Dec-2009	30-Dec-2009	0	02-Jan-2010	04-Jan-2010	FL		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1047Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site urticaria, Urticaria

Symptom Text: Hives appearing on torso and at injection site of VZV. Redness at site of HPV.Reported 7- 8 hrs after immunizations given. Child was administered wt. appropriate dose of benadryl. No facial swelling or respiratory involvment noted.Moc reported child doing well and hives had disapated after benadryl given.Moc noted that child had also been to nail salon to have artificial nails applied after office visit and shots administered. Unknown if this event could have caused this reaction

Other Meds:

Lab Data:

History:

Prex Illness: was a wcc visit

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375661-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Feb-2008	20-Aug-2009	553	02-Jan-2010	04-Jan-2010	FL		15-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Complex partial seizures, Epilepsy, Speech disorder

Symptom Text: My daughter started having issue, when she would speak, she would stop talking and also when she was reading she couldn't make out the words. this was happening like once in a while for several months after her HPV Vaccine.then she was getting these episode several times a day (4-6) we took her to 2 neurologists. Dr. diagnose my daughter with Partial Complex seizure and she is now taking Lamictal for the rest of her life.```1/6/10: Consultation received for date of service 11/11/09. Dx: Partial complex seizures. Pt. presented with episodes of interrupted speech/garbled speech which occur several times per day lasting a few seconds. Describes deja vu feeling before episodes. Paroxysysmal episodes with epileptic activity. EEG to be done.

Other Meds:

Lab Data: MRI/several EEG's blood work

History: None

Prex Illness: My daughter receive her last HPV Vaccine on 2/14/2008.She felt like she was going to faint when she got up. She is now sufferin

Prex Vax Illns: Dizzy~HPV (Gardasil)~3~15.83~Patient

Vaers Id: 375681-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Apr-2007	19-Apr-2007	2	03-Jan-2010	04-Jan-2010	IL		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Adenotonsillectomy, Anxiety, Arthralgia, Asthenia, Candidiasis, Change of bowel habit, Chest pain, Chills, Condition aggravated, Confusional state, Convulsion, Cough, Depression, Diarrhoea, Dizziness, Dyspepsia, Dysphagia, Dysphonia, Dyspnoea, Ear pain, Fatigue, Feeling hot, Fibromyalgia, Gastrooesophageal reflux disease, Headache, Heat exhaustion, Hyperhidrosis, Hypermobility syndrome, Hypersensitivity, Hypersomnia, Hypophagia, Irritable bowel syndrome, Lethargy, Malaise, Memory impairment, Muscle spasms, Myalgia, Myofascial pain syndrome, Nasal congestion, Nausea, Neck pain, Night sweats, Odynophagia, Oropharyngeal pain, Pain, Palpitations, Paraesthesia, Pharyngitis, Pyrexia, Rash, Sleep disorder, Somnolence, Staring, Tinnitus, Urticaria, Vomiting, Weight increased

Symptom Text: Susanne was treated at Centegra hospital in McHenry on the following dates:5/7/07, 5/9/07, 10/26/07, 12/09/07, 02/05/08, 03/12/08, 04/16/08, 04/17/08, 05/08/08, 10/19/08, 11/18/08/04/01/09, 05/18/09, 05/27/09, 05/28/09 through 5/31/09, 09/03/09 9/17/09, 09/20/09, 09/23/09, 10/19/09, 10/23/09, 10/26/09 through 10/28/09, 11/17/09, 11/23/09, 11/24/09, 12/14/09, and 12/25/09 for medical issues relating to adverse reaction to the Gardisil vaccine. She was also treated at Mercy Healthcare of Crystal Lake, McHenry, Woodstock, and Harvard by multiple physicians on the following dates: 04/17/07, 05/16/07, 06/29/07, 10/08/08, 10/15/08, 11/13/08, 01/28/09, 02/11/09, 04/02/09, 05/12/09, 05/28/09, 06/02/09, 06/10/09, 07/02/09, 07/28/09, 08/12/09, 09/14/09, 09/21/09, 09/25/09 by two separate physicians, 10/09/09, 10/12/09, 10/19/09, 11/09/09, 11/16/09, 11/17/09, 11/23/09, 11/30/09, 12/02/09, 12/11/09, 12/14/09, and 01/01/10. Susanne was seen and treated for the following ongoing medical issues: Fibromyalgia, environmental allergic reactions, hoarseness, coughing, shortness of breath, difficulty/pain when swallowing, continued throat pain, dizziness, repeated severe headaches, light headed, chills, overheated, excessive night sweating, lathargic, sleeping for entire day without waking rested, confusion/short term memory issues, seizures, sharp chest pains, racing heart, muscle/joint aches, hives on trunk/arms/shoulders, ringing in ears, severe depression, twisted/spastic colon, acid reflux, heartburn, weight gain. 1/4/2010 GI consult records for 9/14/2009, patient with chronic but progressively worse abdominal pain of ? etiology, increased fatigue, non-specific chest pain, change in bowel movements, alternating constipation and diarrhea, cold sweats and SOB with exertion, weakness with sensation of knees giving away ```1/12/2010 multiple ED visits with dates ranging from 5/2007 to 12/25/2009 , DC summary and Psych consult for 5/28-5/31/2009 multiple c/o's nausea, vomiting, fever, headaches, dizziness, nasal congestion, RL

Other Meds: Clonidine 0.1mg one in AM 1/2 in PM, Levoxyl once daily, Albuterol PRN.

Lab Data: Susanne has recieved treatment from multiple physicians and specialists and at several facilities (listed above). Medical records can be requested from each location. Dx studies: Ct abdomen and pelvis done 6/2009 wnl, Colonoscopy noted a

History: Hypothyroid, Depression, Allergy to Adderal, Rapid Eye Blinking PMH: Depression, Bipolar, Asthma, Hypothyroidism, Hx of tics (blinking frequently) Allergies: Adderal, Lamictal ```1/12/2010 multiple records from PCP, ED visits, Dc summary, MR, ENT, Psych consult ```1/26/10 Received medical records w/PMH: anxiety, behavioral issues. Allergy: augmentin. Family hx: fibromyalgia

Prex Illness: No ```1/12/2010 multiple records from PCP, ED visits, Dc summary, MR, ENT, Psych consult

Prex Vax Illns: Seizures~Influenza (H1N1) (Influenza (H1N1) (UNKNOWN MANUFACTURER))~~10.00~Sibling

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375693-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Jan-2008	01-Mar-2008	53	03-Jan-2010	04-Jan-2010	TX		08-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Acne, Anxiety, Arthralgia, Depression, Dyspepsia, Fatigue, Feeling abnormal, Influenza like illness, Malaise, Myalgia, Ulcer

Symptom Text: Between 1st & 2nd shot of Gardasil patient developed severe stomach pain,cramping, and burning that lasted weeks. Muscle aches and overall feeling of not being well. In August 2009 patient had flu like symptoms, anxiety, depression, fatigue, ulcers, acne, overall feeling of illness or impending death. ```MR received 01/04/10 and 01/05/10 for DOS 09/25/09. Pt c/o pain in both ankles, fatigue, HA, stomach cramps and muscle spasms. Assessment: arthralgia, myalgia.

Other Meds:

Lab Data: All kinds of blood labs, x-rays, stomach scans, ct scan, urine/stool analysis

History: Allergies-Sulfur Drugs ```PMH: R foot hx of trauma, UTI, fell on concrete and had convulsions, asthma. Allergies: sulfa drugs.

Prex Illness: Muscle Aches

Prex Vax Illns:

Vaers Id: **375746-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Dec-2009	22-Dec-2009	0	04-Jan-2010	04-Jan-2010	SC		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: 4pm pt. was given GARDASIL and BOOSTRIX I.M. pt was pre syncope, cold compress applied to forehead. Pt was moved c/o exam room - place on table and lay down. BP 80/50, P 80, 414P BP-90/60, P-580, 420P BP 92/60, P- 80, 425P -pt states she feels better, 430P BP 92/62.

Other Meds: None

Lab Data:

History: None

Prex Illness: Candidiasis of vulva/vagina

Prex Vax Illns: None~ ()~~0.00~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375760-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Dec-2009	02-Jan-2010	3	04-Jan-2010	04-Jan-2010	IA		04-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1100Y	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0672X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Movement disorder, Musculoskeletal stiffness, Neck pain

Symptom Text: Stiff and sore neck, unable to turn head

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 375798-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Sep-2009	21-Sep-2009	4	04-Jan-2010	05-Jan-2010	FL	FL	17-Feb-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU	SANOFI PASTEUR	U3197AB	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334DA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0654X	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2846AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Activities of daily living impaired, Acute disseminated encephalomyelitis, Anxiety, Asthenia, Ataxia, Back pain, Dehydration, Demyelination, Diplopia, Disturbance in attention, Dysstasia, Fatigue, Gait disturbance, Goitre, Headache, Hypoaesthesia, Micturition urgency, Myalgia, Myelitis transverse, Nausea, Neuropsychological test, Paraesthesia, Pollakiuria, Tremor, Ultrasound thyroid abnormal, Urinary incontinence, Vaccination complication, Vision blurred, Vomiting

Symptom Text: 9/21/2009 Sent home from school bad headache, nausea, muscle aches, weakness. 9/29/2009 not allowed to give blood came home early from school nausea & vomiting weak feels numbness all over 9/30/2009 stayed home from school, weak nausea & vomiting feels weak, numbness in legs, difficulty walking 10/1/2009 home from school tingling from trunk into legs, weak, nausea vomiting, difficulty walking 10/2/2009 Back to school, tired weak, numbness 10/3/2009 Resumed vomiting again in the evening 10/5/2009 to pediatrician difficulty walking, nausea, weakness 10/6/2009 ER RX Zofran for nausea sent home 10/7/2009 ER IV hydration sent home 10/8/2009 weakness worsens 10/9/2009 to pediatrician vomiting dehydrated admitted to hospital from pediatrician's office unable to walk/stand. Dr. noted enlarged thyroid U/S thyroid and abdominal -- normal Ct Scan abdomen -- normal 10/10 Blurred vision in left eye 10/11/2009 MRI back -- transverse myelitis 10/12/2009 MRI brain--lesions in brain consistent with A.D.E.M. Spinal tap and start IV Steroids transfer to Hospital 10/13/2009 Diagnosed with Acute Disseminated Encephalomyelitis and Transverse Myelitis Infectious Disease ruled out a viral cause and states consistent with vaccination reaction. 11/05/2009 Consultation at Hospital Multiple Sclerosis Center and A.D.E.M. diagnosis confirmed by pediatric neurologist. 1/6/2010 ED records for 10/6 and 10/8/2009 patient with c/o's nausea/vomiting and diarrhea, IVF, IV Zofran 1/6 and 1/7/2010 MR for 10/9-10/12/2009 patient admitted nausea. vomiting and progressive weakness transferred to another facility for continued care on 10/12/2009 1/6/2010 MR and DC summary for 10/12-10/16/2009, patient with c/o's numbness, weakness, ataxia, nausea/vomiting, tingling and hand tremors, diplopia LP, Neuro and Opthalmology, ID consults, IV Solu-Medrol x 5 days with resolution of sx. dc'd home on steroid taper and f/up with PCP DC DX: Weakness, improving. Ataxia, improving. Numbness improving. Demyelinating disease of CNS. ```1/

Other Meds: None

Lab Data: Blood work to rule out virus all normal Spinal Tap to rule out virus/Multiple Sclerosis no virus detected MRI of Spine and Brain -- confirmed A.D.E.M. Labs: RA factor wnl, HIV negative, Hepatitis A AB +, csf noted ollgocional bands, + f

History: None PMH: None Allergies: NKDA ```PMH: 34 wk premie. Presyncope and anxiety with dehydration age 12

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 375851-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Dec-2009	22-Dec-2009	0	05-Jan-2010	05-Jan-2010	CA		05-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF544AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Immediate post-injection reaction, Rash erythematous, Tremor

Symptom Text: The child was receiving 2 vaccines on same day. She received TDAP first without complaint. She received GARDASIL second and immediately became flushed, developed red rash on neck & shaking. She was alert the entire time.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375868-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	10-Dec-2009	10-Dec-2009	0	05-Jan-2010	05-Jan-2010	WA		05-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929N	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nasal congestion, Wheezing

Symptom Text: Pt. developed wheezing & severe stuffy nose 3 1/2 hrs. after vaccine administered. She was seen after hours at local clinic & given BENADRYL. She called next am to report & stated symptoms resolved.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375886-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Dec-2009	30-Dec-2009	1	05-Jan-2010	05-Jan-2010	TN		05-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2845AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site swelling, Pain in extremity, Pyrexia, Rash erythematous, Vertigo

Symptom Text: L arm swollen at injection site, headache, fever of 102, vertigo, erythematous 4.5 x 4cm, arm pain.

Other Meds:

Lab Data:

History: Acne; allergic-amoxicillin

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375941-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Nov-2009	05-Nov-2009	2	05-Jan-2010	06-Jan-2010	LA		06-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2910AA	1	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	43161DA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	1	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B0391AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Hallucination, Headache, Pyrexia

Symptom Text: Patient seen in ER for weakness, frontal headaches, fever, hallucinating

Other Meds: Allegra D 12 hr

Lab Data: CBC, chem 7, Pt/PTT u/H, pregnancy test

History: environmental

Prex Illness: allergy with rhinitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375974-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	05-Jan-2010	05-Jan-2010	0	05-Jan-2010	06-Jan-2010	CA		06-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Erythema, Feeling hot, Hyperhidrosis, Immediate post-injection reaction, Injection site pain, Pain, Skin discolouration

Symptom Text: At time of Garasil vaccine injection to LD IM pt immediately felt severe pain at site of injection, felt dizzy lighthead, hot and sweaty. Pain 6/10. Within 15 mins time pts color return to lips and face completely. Slight darken redness noted to skin below eyes.

Other Meds:

Lab Data: BP 96/70

History: NKDA/none

Prex Illness: Pale, lightheaded, dizzy, pain at site of inj

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **375981-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Aug-2009	01-Dec-2009	97	06-Jan-2010	06-Jan-2010	VA		25-Jan-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0381X	0	Left arm	Unknown	
MNQ	SANOFI PASTEUR	U3030AA	0	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Arthralgia, Back pain, Conversion disorder, Fall, Muscular weakness, Myelitis transverse, Syncope

Symptom Text: Transverse myelitis. ```1/07/10: ED Records and Discharge Summary received for date of service 11/30/09 to 12/1/09: Final Dx. Lower extremity weakness bilaterally, right hip pain, concern for conversion disorder. Episode started as lower back pain. Slept well, went to school but developed numbness in the lower extremities that became progressively worse untli she collapsed, no LOC, unable to walk. Lower extremity strength exam reveals diffuse weakness bilaterally. MRI's of lumbar and thoracic spine were normal and not consistent with GBS, therefore a psychiatric evaluation was recommended to r/o conversion disorder. Transferred to another medical facility for care. ```1/20/10 Discharge Record and Medical Records received for dates of service 12/1/09 to 12/8/09. Dx: Transverse myelitis. Presented with 2 day history of bilateral lower extremity weakness. The day before admission, legs felt like they were asleep. On day of admission she became weak and collapsed while at school. Treated with methylpredisolone. Discharged with resolution of weakness.

Other Meds:

Lab Data: MRI. ```1/07/10: ED Records and Discharge Summary received for date of service 11/30/09 to 12/1/09: Labs and diagnostics: Lumbar and thoracic MRI's-WNL. UA-Normal. Drug screen-negative. ESR 18(H). Alk.Phos. 131(H). CAT Scan-Pelvis-W

History: None. ```1/07/10: ED Records and Discharge Summary received for date of service 11/30/09 to 12/1/09: PMH: Allergy to artificial sweeteners.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 376004-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Jun-2009	25-Jun-2009	3	06-Jan-2010	07-Jan-2010	KY	WAES0909USA04914	29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Aura, Dizziness, Dyskinesia, Dyspnoea, Erythema, Facial palsy, Fatigue, Feeling abnormal, Feeling hot, Flushing, Heart rate increased, Hyperventilation, Hypoaesthesia, Hypokalaemia, Joint contracture, Loss of consciousness, Memory impairment, Muscle spasms, Musculoskeletal stiffness, Myalgia, Palpitations, Panic attack, Paraesthesia, Postictal state, Presyncope, Respiratory rate increased, Sinus bradycardia, Somnolence, Speech disorder, Staring, Tachypnoea, Tremor, Unresponsive to stimuli

Symptom Text: Information has been received from a physician concerning a 15 year old female patient, who on 22-JUN-2009 was vaccinated with the first 0.5 ml dose of GARDASIL, intramuscularly. Concomitant therapy included ALEVE and ALLEGRA. On 25-JUN-2009 the patient had a 5 minute period where she was unresponsive, her fingers were stiff and she was generally dazed. On 18-AUG-2009 the patient was given a second 0.5 ml dose of GARDASIL, intramuscularly. On 20-AUG-2009 she had a similar episode that lasted 15-20 minutes. On 06-SEP-2009, the patient had another episode that lasted 30-40 minutes. She was brought to an ER. The hospital staff told her that they thought that is was a panic attack and told her to take potassium supplements. The mother decided to not complete the series. At the time of reporting the patient had recovered. Follow up information has been received from a physician via medical records concerning the patient with penicillin allergy and smoker who on 22-JUN-2009 was vaccinated with the first dose of GARDASIL (Lot number 0702X) IM in the left deltoid and on 18-AUG-2009 with the second dose of GARDASIL (Lot number 0162Y) IM in the right deltoid. Concomitant therapies included albuterol and multivitamin. On 06-SEP-2009, the patient presented to the emergency room with chief complaint of possible anxiety, trouble breathing. The patient was sitting in church and began having trouble breathing. Patient began increased breathing. The patient began tingling of face and contracture of hands. The patient had trouble talking. The episode resolved after breathing slowed. At the ER, the patient felt hot. The patient had similar episode recently at school, 2 weeks ago stated by the mother and lasted 10 minutes. The patient's initial temperature was 99.4, pulse 115, respiration 28, blood pressure 142/105 and SaO2 100 and the discharge pulse rate was 62, respiration 16, blood pressure 124/84 and SaO2 was 100. Electrocardiogram was performed and showed sinus bradycardia with a heart rate of 58 bmp. The neurological/physiolo

Other Meds: Albuterol; ALLEGRA; ALEVE; vitamins (unspecified)

Lab Data: Blood pressure, 09/06/09, 142/105, initial; blood pressure, 09/06/09, 124/84, discharged; electrocardiogram, 09/06/09, see narrative; physical examination, 09/06/09, normal; blood pressure, 09/08/09, 116/70; diagnostic laboratory, 09/08/09,

History: ```1/15/2010 received correspondence from vaccine manufacturer dated 11/24/2009 to MD requesting MR for patient regarding adverse reaction to vaccine, ED records for 11/20/2009, Neurology consult notes 11/18/2009/ and 1/5/2010. PCP records, final dx Near syncope with associated hyperventilation syndrome PMH: Asthma Allergies: PCN

Prex Illness: Penicillin allergy; asthma; smoker ```1/15/2010 received correspondence from vaccine manufacturer dated 11/24/2009 to MD reques

Prex Vax Illns:

Vaers Id: **376009-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.3	F	26-Jun-2008	12-Mar-2009	259	06-Jan-2010	07-Jan-2010	IA	WAES0807USA04523B1	17-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Hydronephrosis, Surgery

Symptom Text: Information has been received from a consumer concerning her baby daughter who on 26-JUN-2008 was exposed via her mother who was intramuscularly vaccinated with her first dose of GARDASIL vaccine. Concomitant therapy included cephalexin. The consumer reported that, on 12-MAR-2009, she had her baby girl "but she had some problems"; the baby had hydronephrosis in her kidneys and had two surgeries. The baby was "doing fine now". The mother's experience has been captured in WAES 0807USA04523. Additional information has been requested. This report was previously sent to the PLA V501 on 25-NOV-2009 in WAES #0807USA04523.

Other Meds: Cephalexin

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **376010-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	24-Sep-2009	24-Sep-2009	0	06-Jan-2010	07-Jan-2010	FR	WAES0912USA03196	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0772X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Apnoea, Immediate post-injection reaction

Symptom Text: Information has been received from an agency concerning a female patient with no previous medical history reported who on 24-Sep-2009 was vaccinated with a second dose of GARDASIL (Lot # 0772X, Batch # NK15900). On the same day, immediately after vaccination, the patient lamented lack of breath. The outcome was not reported. The case is closed. Upon internal review, a corrective version was created on 29-DEC-2009. The case was reported as non serious by both HA and the reporter and upgraded to serious by company based on internal rules. Upon internal review apnea was considered to be an other important medical event. No further info is available. Other business partner included E2009-11483.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 376011-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	25-Nov-2009	25-Nov-2009	0	06-Jan-2010	07-Jan-2010	FR	WAES0912USA03789	07-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Dyspnoea, Throat irritation, Urticaria

Symptom Text: Initial case was reported as serious on 30-DEC-2009 by Health Authority (NO-NOMAADVRE-FHI-2009-8819/FHI09-2869). This case was also reported as part of a line listing after administration of GARDASIL during the period 15-NOV-2009 to 30-DEC-2009 (same HA ref). It was reported that an 11 year old girl was vaccinated with GARDASIL (second dose, batch number not reported, parental route, 1 DF) on 25-NOV-2009. HA coded abdominal pain, breathing difficult, itching (verbatim: itching throat) and urticaria (causalities possible) with onset on 25-NOV-2009, except for the breathing difficulty which lasted for 30 minutes. Tests performed on 25-NOV-2009: thrombocyte count 226 (no unit reported), eosinophil count 0 (no unit reported), hemoglobin 12.3 (no unit reported), blood pressure normal, pulse rate 90 (no unit reported), neutrophil count 3.2 (no unit reported), white blood cell count 6.5 (no unit reported) and oxygen saturation normal. Respiratory sound normal. The girl was treated with antihistamine (manufacturer unknown) (information not reported), PREDNISOLON (information not reported) and AIROMIR (information not reported) (no indications specified). GARDASIL, dose one, was given without any adverse events (no details on date etc. reported). The patient had previously experienced episodes of urticaria, unknown cause. The outcome is recovered. No further information is available. Case is closed. Other business partner numbers included: E2009-11928.

Other Meds: Unknown

Lab Data: blood pressure measurement, 25Nov09, normal; WBC count, 25Nov09, 6.5; arterial blood O2 saturation, 25Nov09, normal; eosinophil count, 25Nov09, 0; hemoglobin, 25Nov09, 12.3; neutrophil count, 25Nov09, 3.2; platelet count, 25Nov09, 226; tota

History: Urticaria

Prex Illness:

Prex Vax Illns:

Vaers Id: 376012-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Dec-2009	20-Dec-2009	4	06-Jan-2010	08-Jan-2010	FR	WAES0912USA03791	08-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyskinesia, Familial risk factor, Loss of consciousness, Malaise, Muscle spasms, Muscular weakness, Myalgia, Nausea, Tetany, Vertigo

Symptom Text: Case received from a pharmacist in a foreign country on 30-DEC-2009: The reporter's daughter, a 16 year old female patient experienced tetany and spasmophilia after she had received the first dose of GARDASIL (batch number not reported) on 16-DEC-2009. She had no history of sleep disorder. Her father had a history of tetany and spasmophilia. The patient was practicing ski at the time of events but did not fall. Four days after vaccination she presented with vertigo, malaise, loss of consciousness, feeling like vomiting, muscle weakness, muscle pain and abnormal movement of the arms and legs. She could not stay on her feet. Each time she stood up, she experienced vertigo or lost consciousness. On 25-DEC-2009 she was hospitalized for three days. Tests found normal blood sugar, normal calcium and magnesium levels; EEG was normal. Inflammatory markers, CPK, bacterial and viral serologies were not tested. Diagnoses of tetany and spasmophilia were suggested in hospital. As the symptoms persisted, the paediatrician was called for further investigations. At the time of report the patient had not recovered. Other business partner numbers included: E2009-11935.

Other Meds: Unknown

Lab Data: Electroencephalography, normal; Blood glucose, normal; Plasma calcium, normal; Serum magnesium, normal

History: Tetany; Spasmophilia

Prex Illness:

Prex Vax Illns:

Vaers Id: 376036-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	25-Jan-2009	27-Jan-2009	2	06-Jan-2010	06-Jan-2010	FL		06-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injection site anaesthesia, Pyrexia

Symptom Text: Fever, Numbness of Right arm(one used for injection and Numbness of Left leg.

Other Meds:

Lab Data: none

History: Allergic to Penicillin.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376070-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Oct-2009	26-Oct-2009	25	06-Jan-2010	06-Jan-2010	PA		02-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1702X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysarthria, Facial palsy, Photophobia

Symptom Text: unable to eat cereal - milk dripped out of mouth, left side of face drooping, unable to react to sunlight, slurred speech, called primary care doctor - referred to ER, where diagnosed with Bell's Palsy. prescribed prednisone and acyclovir. ```1/8/2010 PCP records for 10/19 and 11/23/2009 Dx Bell's palsy per Dr's notes patient seen in ED on 10/26/2009, dx'd with Bell's palsy, given prednisone and acyclovir for tx, per Dr will hold 2nd Gardisil injection.

Other Meds:

Lab Data: CTscan, blood test, urine tests, neurologist, lime disease test ```1/8/2010 PCP records for 10/19 and 11/23/2009 Dx Bell's palsy

History: None ```1/8/2010 PCP records for 10/19 and 11/23/2009 Dx Bell's palsy PMH: None Allergies: NKDA

Prex Illness: No ```1/8/2010 PCP records for 10/19 and 11/23/2009 Dx Bell's palsy

Prex Vax Illns:

Vaers Id: **376071-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Dec-2009	16-Dec-2009	1	06-Jan-2010	07-Jan-2010	CA		25-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU(H1N1)	SANOFI PASTEUR	UPO22AA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0672Y	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Pt was to be given 3rd HPV and H1N1. Pt's sibling was also going to get same vaccines. Pt. was agittaged because she didn't want to get shots. LVN gave pt 2 injections on left deltoid. He immediately told RN that he accidently gave pt. 2 HPV's instead of H1N1 and HPV. Mother was notified MD notified. No adverse reaction. Pt received 2 HPV's and (H1N1).

Other Meds:

Lab Data: None

History: Dev disorder with speech delay

Prex Illness: None

Prex Vax Illns:

Vaers Id: 376090-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Jan-2010	04-Jan-2010	0	06-Jan-2010	07-Jan-2010	NC		11-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1109Y	1	Left arm	Subcutaneously	
	HEPA	MERCK & CO. INC.	1257Y	1	Right arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Cough, Dizziness, Dry mouth, Dyspnoea, Flushing, Heart rate increased, Urticaria, Wheezing

Symptom Text: BECAME FLUSHED, C/O DIFFICULTY BREATHING, WHEEZING AND DEVELOPED HIVES ON TRUNK AND EXTREMITIES REQUIRED PROLONGED OBSERVATION AT MD OFFICE. GIVEN 0.5ML (1:1,000) EPINEPHRINE SQ, 50 MG BENEDRYL PO, ORAPRED 60 MG X1 DOSE. ```MR received 1/11/10 for 1/4/10. CC: pt received vax x3, then pt c/o flushing face, then dizzy, cough, started to c/o SOB, wheezing, dry mouth, then pt had hives at injection site. Assessment: chest clear, normal voice, (+)hives, HR increased, epi pen given, hives decreased, lungs clear, VSS hives gone, pt sent home stable.

Other Meds: NONE

Lab Data:

History: 32 WEEK PREEMIE, CONGENITAL HYDROCEPHALUS, VP SHUNT

Prex Illness: NO

Prex Vax Illns: WHEEZING, FACIAL SWELLING~Influenza (Seasonal) (no brand name)~~3.75~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376312-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Jan-2010	06-Jan-2010	0	08-Jan-2010	08-Jan-2010	LA		21-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site pruritus, Injection site swelling

Symptom Text: 1 day after injection noticed swelling redness, and itching and became tender to touch Lt deltoid area.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376362-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	30-Dec-2009	31-Dec-2009	1	09-Jan-2010	11-Jan-2010	NV		11-Jan-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3053AA	0	Unknown	Intramuscular	
FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	102128P1	0	Unknown	Intramuscular	
FLUN	MEDIMMUNE VACCINES, INC.	500733P	0	Unknown	Unknown	
HPV4	MERCK & CO. INC.	1099Y	0	Unknown	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cyanosis, Dizziness, Fatigue, Nausea, Pallor, Pyrexia, Vomiting

Symptom Text: Vomitting 2 times; nausea, pale face and blue lips for 6 hours; dizzyness, fever, fatigue for 4 days

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 376406-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	13-Nov-2007	25-Nov-2007	12	10-Jan-2010	11-Jan-2010	MA		18-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	0	Right arm	Intramuscular	FLU
	TDAP	SANOFI PASTEUR	C2862AA		Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Bladder disorder, Dry eye, Fatigue, Flatulence, Food intolerance, Hypertonic bladder, Micturition urgency, Musculoskeletal stiffness, Myalgia, Nocturia, Pollakiuria, Rhinitis, Skin laceration, Somnolence, Steatorrhoea, Tendon pain, Urinary tract infection, Vaccine positive rechallenge, Wheezing

Symptom Text: About a week after the first shot I started to have Achilles pain which I had never had before. Several weeks later, I started having problems controlling my bladder. I had increased frequency and urgency. I had to start wearing diapers because I kept losing control. Muscle soreness also increased all over my body. My body was very stiff. I was a collegiate athlete and suddenly I felt like a prisoner trapped in my own body, unable to move. After each shot, my symptoms worsened. I became increasingly tired all of the time and only wanted to sleep during the day. My eyes were also extremely dry and I would get cuts all over my hands-signs of arthritis. ```MR received 1/14/10 for dates 3/11/08, 4/22/08. DX: overactive bladder syndrome, UTI. CC: pt states had UTI in 11/07, tx and resolved, then 2 months later had reoccurrence of sx but negative urine culture, and again in April 08. Currently, less burning sensation but pt c/o frequency/urgency, pressure, nocturia. Recently pt had inability to control leakage. OV 3/11/08: DX: food intolerance/malabsorption, asthma, rhinitis, steatorrhea. CC: pt c/o possible multiple food allergies causing abdominal pain, gas pain. Poss dust allergy w/ c/o wheezing.

Other Meds: Adderall 20mg

Lab Data: 3/10/08 UTI 3/11/08 Food Allergies (IgE testing) 4/22/08 Overactive Bladder (misdiagnosis) 5/25/08 Reactive Arthritis or Ankylosing Spondylitis 3/10/09 Mediator Release Test

History: Asthma, ADHD ```MR received 1/14/10 PMH:anxiety, depression, asthma.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376524-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Aug-2008	25-Dec-2008	120	11-Jan-2010	12-Jan-2010	IL		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0845X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature decreased, Erythema, Pain, Pruritus, Urticaria

Symptom Text: Dec 25 2008 how shower produced red itchy welts. Jan 1st 2009 to present time. Cold temp 35 degrees or below when outside for more than a few minutes. Red welts that are itchy and painfully appear. Last about 30 mins after body warms up.

Other Meds: None

Lab Data: Spoke with Dr Dec 10 2009. We discussed it as side effects from GARDASIL, she advised to report it here

History: Stroke at birth nothing else

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376541-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Nov-2009	Unknown		11-Jan-2010	12-Jan-2010	--		12-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Left arm	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	U3010AA	0	Left arm	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	C3029BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Pruritus, Rash erythematous

Symptom Text: Within 12 hours of giving vaccines pt developed abdominal cramping. Parents beleive it was the day after the vaccines were given that the pt developed an itchy diffuse red rash on left arm about the size of an adult hand that resembled a "wind burn"

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376574-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Dec-2009	08-Dec-2009	0	12-Jan-2010	12-Jan-2010	WA		12-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainting

Other Meds: Unknown

Lab Data:

History:

Prex Illness:

Prex Vax Illns: Fainting~HPV (Gardasil)~1~15.00~Sibling

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376586-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-Oct-2009	03-Oct-2009	2	12-Jan-2010	12-Jan-2010	FL		12-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Pain, Rash

Symptom Text: Pt developed rash on arms and torso two (2) days after injection; rash lasted 'couple more days'. Pt felt "flush and achy".

Other Meds: CIPRO 250 mg BID x 3 days; DESOGEN

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **376611-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Jan-2007	15-Oct-2008	639	12-Jan-2010	12-Jan-2010	FL		15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0244U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Back pain, Convulsion, Dysphemia, Loss of consciousness, Muscle rigidity, Pyrexia, Tonic clonic movements, Tremor

Symptom Text: Development of seizure like symptoms with muscle rigidity & LOC. February 2007 started with abnormal & continued with back pain. Oct 2008 started fever & sz symptoms. ```1/13, 1/14 and 1/22/2010 PCP, Neurology MD records, ED record for 2/12/2009, Impression: possible seizures patient with c/o's tonic-clonic activity, stuttering and temors

Other Meds:

Lab Data: Negative EEG, CT scan neg. EKG neg. MRI head negative. ```1/13, 1/14 and 1/22/2010 PCP, Neurology MD records, ED record for 2/12/2009, Labs: CBC, BMP, EBV, urine drug screen all negative Dx studies: Ct head , EKG and EEG wnl

History: None ```1/13, 1/14 and 1/22/2010 PCP, Neurology MD records, ED record for 2/12/2009, PMH: None Allergies: Amoxicillin

Prex Illness: None ```1/13, 1/14 and 1/22/2010 PCP, Neurology MD records, ED record for 2/12/2009,

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376617-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Jan-2010	06-Jan-2010	0	12-Jan-2010	12-Jan-2010	TX		12-Jan-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	101BY	2	Right arm	Unknown	
VARCEL	MERCK & CO. INC.	1074Y	1	Right arm	Unknown	
FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500829P	0	Unknown	Unknown	
FLU	SANOFI PASTEUR	43272BA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Ear pain, Immediate post-injection reaction, Pain, Pain in jaw

Symptom Text: Patient received her 3rd dose of the HPV vaccine and immediately reports sharp, shooting pain @ bilateral ears and jawline. Also, c/o lightheadedness. Pt sat for 20 min and symptoms resolved after 5-10 min.

Other Meds:

Lab Data: BP check WNL

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376647-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Jan-2010	05-Jan-2010	0	12-Jan-2010	12-Jan-2010	MA		26-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU(H1N1)	SANOFI PASTEUR	UP057AA	0	Right arm	Intramuscular	FLU
	HPV4	MERCK & CO. INC.	0652X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Fatigue, Feeling abnormal, Lethargy, Muscular weakness, Musculoskeletal stiffness, Neck pain, Palpitations, Paraesthesia, Somnolence, Tremor

Symptom Text: Night vaccines were delivered. Patient complained of light headed and "weird". Woke next am with same feeling. Progressed to weakness in legs, stiffness in thighs, sore neck and sensation of touch had changed. Patient stated felt like entire body was "asleep". Patient seen in PCP office 1/6/10, had difficulty staying awake during exam. Increased lethargy and weakness while in office. Sent to ER. Patient was evaluated by neurology in ER with normal V/A, toxin screen, EKG, normal neurological exam. Patient given 1L IV fluid, improved and was discharged. ```1/14, 1/15 & 1/18/10. PCP and ED records received for dates of service 1/6/10. Dx: Weakness, lethargy, fatigue. Presented with light-headedness, feeling "weird," legs weak and back of thighs stiff, back of neck sore, sensation of touch is altered. Felt like whole body was asleep. Had palpitations and trembling morning of ED visit. Treated with 1 L IV Fluid and discharged.

Other Meds: ORTHOCYCLIN; hydrocortisone

Lab Data: UA negative, urine tox screen. negative, EKG normal sinus rhythm, CBC and chem 10 both within normal limits. ```1/14, 1/15 & 1/18/10. PCP and ED records received for dates of service 1/6/10. Labs and diagnostics: MRI Brain-Abnormal.

History: pituitary micro adenoma; depression; anxiety; eczema; vascular congenital hematomas. ```1/14, 1/15 & 1/18/10. PCP and ED records received for dates of service 1/6/10. PMH: 31 week infant.

Prex Illness: abdominal pain

Prex Vax Illns:

Vaers Id: **376650-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Mar-2009	16-Nov-2009	244	12-Jan-2010	13-Jan-2010	CA	WAES0905USA00390	13-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1005X		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal disorder, Pulse absent

Symptom Text: Information has been received from a nurse for the Pregnancy Registry for GARDASIL concerning a 15 year old female who on 17-MAR-2009 was vaccinated with the first dose of GARDASIL 0.5ml IM (therapy site unknown) (Lot # 661760/0652X). The nurse reported that the patient received her first does of GARDASIL and then discovered she was pregnant. She sought medical attention. Urine test performed at the office on 04-MAY-2009 (results positive). No adverse effects reported. Follow-up information has been received from a physician concerning a 15 year old female who on 17-MAR-2009 was vaccinated with the first dose of GARDASIL 0.5ml IM (therapy site unknown) (Lot # 661766/06652X) and VARIVAX (MSD) (therapy dose, route and site unknown) (Lot#661558/1005X). The patient's last menstrual period (LMP) was on 01-MAR-2009 and the estimated delivery date is 06-DEC-2009. The patient had no previous pregnancies, spontaneous abortions, or fetal deaths (stillbirths). Follow-up information has been received from a physician. The patient's last menstrual period (LMP) was changed from 01-MAR-2009 to 20-FEB-2009 and the estimated delivery date was changed from 01-DEC-2009 to 27-NOV-2009. Follow-up information has been received from a physician concerning a 15 year old female with no significant concurrent conditions or medical history who on 17-MAR-2009 was vaccinated with the first dose of GARDASIL 0.5ml IM (therapy site unknown) (Lot # 661766/0652X) and VARIVAX (MSD) (therapy dose, route and site unknown) (Lot # 661558/1005X). On 09-JUN-2009 prenatal testing ultrasound was performed (results unknown). The patient's last menstrual period (LMP) was changed from 20-FEB-2009 to 01-FEB-2009 and the estimated delivery date was changed from 27-NOV-2009 to 06-DEC-2009. The physician noted the patient had no previous pregnancies. Follow-up information has been received from a physician concerning a 16 year old female student who on 17-MAR-2009 was vaccinated with the first dose of GARDASIL IM (therapy site unknown (Lot # 661766/0652X). On 16

Other Meds: Unknown

Lab Data: urine beta-human, 05/04/09, positive; Apgar score, 11/16/09, 9

History:

Prex Illness: Pregnancy NOS (LMP - 3/1/2009)

Prex Vax Illns:

Vaers Id: 376651-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jul-2009	01-Jul-2009	0	12-Jan-2010	13-Jan-2010	FR	WAES1001CAN00003	13-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, Headache, Injection site pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a pharmacist concerning a 17 year old female who in July 2009 was vaccinated with the first dose and September 2009 was vaccinated with the second dose of GARDASIL, lot number(s) not available. In July 2009 the patient experienced headache and pain at injection site. In September 2009 the patient experienced headache and pain at injection site. On 27-DEC-2009 the patient experienced a GRAND mal seizure (reported as since December 27 has had four Grand mal seizures). On approximately 27-DEC-2009 the patient experienced Grand mal seizure. On approximately 28-DEC-2009 the patient experienced Grand mal seizure. On approximately 29-DEC-2009 the patient experienced a Grand mal seizure. The pharmacist reported that the patient had no history and a clean CAT scan (no other details provided) and that she was looking at all possibilities. Upon internal review, Grand mal seizure was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Computed axial tomography, 27?Dec09, clean

History: none

Prex Illness:

Prex Vax Illns:

Vaers Id: 376657-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Jan-2010	05-Jan-2010	1	12-Jan-2010	13-Jan-2010	TX		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y		Right arm	Intramuscular	
	FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	100922	0	Left leg	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Areflexia, Asthenia, Balance disorder, Blood product transfusion, Drooling, Facial paresis, Fatigue, Gait disturbance, Guillain-Barre syndrome, Hypoaesthesia facial, Hyporeflexia, Malaise, Mastication disorder, Miller Fisher syndrome, Muscular weakness, Neutropenia, Positive Rombergism

Symptom Text: Muscular Weakness, starting from lower extremity and spreading upwards. Patient reported difficulty climbing stairs when previously there was no problem. Suspicious of Guillain-Barre Syndrome. Hospitalized, decreased tendon reflexes and decreased facial muscle strength noted as well on admission. Given 5-day IVIG treatment with significant symptom improvement. ``` Hospital records, neurology consult, discharge summary received 1/22/10, 1/28/10. Service dates 1/9/10 to 1/14/10. Diagnosis: Guillain-Barre Syndrome, Miller Fisher varient. Patient presents with biliateral leg weakness that intereferes with going up stairs. Has progressed to arm and right-sided facial weakness. Drooling and difficulty chewing. DTRs reduced upper extremities, absent lower extremities. Unsteady, sways with Romberg. IVIG administration. Stable, discharged to home. ``` PCP, vaccine records received 1/13/10. Service dates 12/7/09 to 1/5/10. Lack of energy, numbness right side of face. Tired, not feeling well. Neutropenia.

Other Meds:

Lab Data: Decreased/absent Deep Tendon reflexes Elevated CSF Protein levels with non-elevated CSF cell counts ``` LABS and DIAGNOSTICS: CSF - WBC diff, RBSs present, Protein 73 MG/DL (H). CMV AB IGM (+), IGG (+). EBV IGG >10240 1:NN (H). IGM 181.

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376713-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Nov-2009	06-Nov-2009	0	12-Jan-2010	13-Jan-2010	WA		13-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2913AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0968Y	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0384Y	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site swelling

Symptom Text: Pt received VARIVAX vaccine (2nd dose) on 11-6-2009: according to the pt's mother "she swelled up @ injection site 3 hours later. Pt was taken to the MD who prescribed warm compress & pt to stay away from VARIVAX vaccine.

Other Meds: PCS

Lab Data: None

History: PCN

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376731-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	M	12-Sep-2007	03-Apr-2009	569	13-Jan-2010	14-Jan-2010	FR	WAES0908USA03588B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0870F	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cleft palate, Drug exposure during pregnancy

Symptom Text: Initial case was reported on 19-AUG-2009 by consumer to company representative. Further information was received from a nurse on 20-AUG-2009. It was reported that a baby was born on 03-APR-2009 through a normal and uncomplicated birth. He weighted 3440g and was 49cm tall. The boy was born with cleft palate and will undergo some surgery for event in the near future. His mother was vaccinated with GARDASIL, dose 1 (batch number NE43150, lot # 654883/0870F) on 12-SEP-2007, dose 2 (batch number NF27900, lot# 1537F) on 15-NOV-2007 and dose 3 (batch number NG22850, lot# 0510U) on 12-MAR-2008. A few months later she got pregnant. During the pregnancy she developed a facial paresis. Cleft palate was considered to be a congenital anomaly. The mother's experience has been captured in WAES# 0908USA03588. No further information is available. Case is closed. Other business partner numbers include E2009-08171.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376734-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Nov-2008	Unknown		13-Jan-2010	14-Jan-2010	FR	WAES1001USA00416	14-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal distension, Ovarian cancer, Ovarian cyst, Surgery

Symptom Text: Information has been received from a general practitioner concerning a 17 year old female patient with no family history of ovarian cancer who on 15-NOV-2008 and on 06-FEB-2009 was vaccinated with the first and second doses of GARDASIL (batch number, lot number not provided). The patient was not on contraceptives at time of reporting. On an unspecified date, the patient experienced significant abdominal distension. MRI was very suggestive of a malignant lesion. Ovarian cancer was consequently suspected. The patient underwent surgical operation in December 2009: genital organs were preserved and the surgeon specified that it was probably a non-malignant cyst. Anatomopathological results were awaited. The outcome was not reported at the time of reporting. The patient's ovarian cancer, abdominal distension, and ovarian cyst were considered other important medical events. Other business partner number included: E200911947. Additional information has been requested.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, suggestive of a malignant lesion

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376744-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
35.0	F	21-Sep-2009	01-Dec-2009	71	13-Jan-2010	14-Jan-2010	FR	WAES1001TWN00004	03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Blighted ovum, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer concerning a 35 year old female who on 21-SEP-2009 was vaccinated with the third dose of GARDASIL. The patient subsequently became pregnant. Date of LMP was reported as 19-OCT-2009 and estimated delivery date was 26-JUL-2010. In December 2009, the patient experienced blighted ovum and spontaneous abortion. Upon internal review, blighted ovum and spontaneous abortion were considered other important medical events. No further information is available.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 19Oct09)

Prex Vax Illns:

Vaers Id: **376847-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		14-Jan-2010	15-Jan-2010	MD	WAES1001USA00365	16-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Arthropathy, Headache, Hypoaesthesia, Myalgia

Symptom Text: Information has been received from a physician concerning a female patient with no pertinent medical history and no known allergies who on an unknown date was vaccinated with a second dose of GARDASIL (Lot # not reported). Concomitant therapy included isoniazid, 2 months prior to getting first dose of GARDASIL, had been on isoniazid for 4 months total. A few days after receiving the second dose of GARDASIL, the patient experienced diffused muscle pain, arthralgia, knees hurt, difficulty with joints and had headaches. The physician believed significant disability because the patient "could not function anymore and not getting out of the house". The physician also mentioned that the patient did not have any problems after the first dose of GARDASIL. The patient sought medical attention by an office visit. A "blood work" test was performed which was normal. At the time of the report, the outcome of the patient was not recovered. The health care professional contacted during telephone follow-up could not supply the following information: dates of vaccination, lot numbers and date of event. No further information is available. ```MR received 01/20/10 and 01/22/10 for DOS 01/04/10. DX: Pt presented to ED with hand numbness, HA, pain in both wrists, arthalgias, myalgias, arthropathy. Tx: Aleve.

Other Meds: Isoniazid

Lab Data: Hematology, "blood work" was normal ```DX studies: CXR: negative, Rheumatoid factor: negative.

History: ```PMH: Allergies: none.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376848-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		14-Jan-2010	15-Jan-2010	TX	WAES1001USA00262	15-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Corneal lesion, Multiple sclerosis, Muscular weakness

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who was vaccinated with 3 doses of GARDASIL. Physician stated client went to his office in October 2009 presenting muscle weakness and a patch on her cornea, unspecified cornea. The physician reported that at that time, the patient's mother told her child was healthy until then. The physician stated that the client may have developed Multiple Sclerosis. Client was referred to neurologist. The patient outcome is unknown. Patient sought medical attention. Upon internal review, Multiple Sclerosis was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **376942-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Jan-2010	11-Jan-2010	0	14-Jan-2010	15-Jan-2010	NY		17-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Vomiting

Symptom Text: Received shot 1.11.10 @ 4pm and reported fever (103.2) and vomiting at about 9pm. Message taken at 9a 1.12.10

Other Meds:

Lab Data:

History:

Prex Illness: None reported

Prex Vax Illns:

Vaers Id: 377069-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Jan-2010	05-Jan-2010	0	15-Jan-2010	19-Jan-2010	MA	WAES1001USA00261	19-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	UNKNOWN MANUFACTURER	U3366AA		Unknown	Unknown	
	FLU(H1N1)	UNKNOWN MANUFACTURER	UP057AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1318Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: Information has been received from a physician and a nurse concerning a 15 year old female patient with unspecified psychological trauma, with a medical history of positive varicella and low vitamin D and with no known drug allergies, who on 10-SEP-2009, was vaccinated with the first dose of GARDASIL (663451/0216Y). Concomitant vaccine therapies included : RECOMBIVAX HB (manufacturer unknown) (Lot No: 664738/0650Y) and Td (Lot No: A023B). No problems were noted after vaccination. On 05-JAN-2010, the patient was vaccinated with the second dose of GARDASIL (Lot No: 665547/1318Y). Concomitant vaccine therapies included influenza virus A (antigen type unspecified) vaccine (H1N1) (Lot No: UP057AA) and influenza virus vaccine (unspecified) (Lot No : U3366AA). The physician reported that after the patient received her second dose of GARDASIL, on 05-JAN-2010, she curled into the "fetal position" and stated that she could not get up". She was also experiencing dizziness and a headache. The physician also reported that after 2 hours, the patient still could not get up so she was taken to the ER by an ambulance. On the same day, 05-JAN-2010, blood pressure and pulse were taken (no results were reported). No treatment was given in the office. The nurse reported that she did not see any "patient's fetal position curling" and she stated that the patient may had been dramatizing for the physician. In the ER, the patient was observed for four hours and no treatment was required. The patient was not admitted. The nurse also reported that on 07-JAN-2010, she spoke to the patient's mother and stated that her daughter recovered except for a minor headache. The patient sought medical attention and was seen by the physician at a hospital. The physician considered "Curled into the fetal position and could not get up", dizziness and headache as other important medical events since the patient was rushed to the hospital in an ambulance. No further information is available.

Other Meds:

Lab Data: blood pressure, 01/05/10; total heartbeat count, 01/05/10

History: Vitamin D deficiency; Varicella

Prex Illness: Psychological disorder NOS

Prex Vax Illns:

Vaers Id: 377070-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	11-Aug-2009		15-Jan-2010	19-Jan-2010	FR	WAES1001USA00930	19-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Right arm	Intramuscular	
	DTP	UNKNOWN MANUFACTURER	NULL		Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Body temperature normal, Cough, Diarrhoea, General physical health deterioration, Headache, Hypokinesia, Influenza like illness, Meningism, Muscular weakness, Musculoskeletal stiffness, Pain in extremity, Pharyngeal erythema, Rhinitis

Symptom Text: Case received from the Health Authority on 07-JAN-2010. It was reported by a pediatrician that a 17-year-old patient was vaccinated with a dose of GARDASIL (manufacturer unknown, lot no. not reported). I.M into the right arm and concomitantly with a booster dose of diphtheria toxoid and pertussis acellular vaccine and poliovirus vaccine inactivated and tetanus toxoid (manufacturer unknown, lot-no. not reported) I.M. into the left arm on 11-Aug-2009 in the afternoon. In the evening post vaccination the patient began to developed increasing pain and weakness in both arms, especially at the right site and in the night post vaccination she experienced severe back pain. The next day in the morning she additionally experienced headache and impaired movement of both arms and upper body. She was hospitalized on 12-AUG-2009. Physical examination revealed subfebrile temperature, a reduced general condition, a reddened throat, mild neck stiffness and inability to do the "knee kiss". The ophthamological examination was without pathological findings. The patient was treated with PERFALGAN, DORMICUM and ibuprofen infusions. Different diagnoses of a vaccination reaction or viral infection were assumed by the hospital physicians. The paediatrician stated the symptoms as meningeal irritation with positive meningitis signs. On 13-AUG-2009 the symptoms improved and on 14-AUG-2009 the girl had completely recovered and was discharged. The patient had been in a foreign country from 01-AUG-2009 to 08-AUG-2009. Within that time she experienced flu-like symptoms with cough, rhinitis, diarrhoea and pain in limbs for just one day. File is closed. No further information is available.

Other Meds: Unknown

Lab Data: Laboratory results were pathological for CRP (6.0 mg/L), hemoglobin (7.8 g/dl), leukocytes (13.0/nl) and MCHC (22.3 g/dl). No normal values were reported. IgG, IgA, IgM and labumin were without pathological findings (no values reported). CS

History: Flu-like symptoms; Foreign travel

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377129-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Jan-2010	18-Jan-2010	0	18-Jan-2010	19-Jan-2010	LA		19-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Unresponsive to stimuli

Symptom Text: 09:04 AM-Turned to find patient lying on her side/back-unresponsive with arms jerking, lasted approximately 4 seconds. Pt. sat up immediately and was AAO x 3.

Other Meds: Doxycycline for acne

Lab Data:

History: Anxiety

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377130-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jan-2010	15-Jan-2010	1	18-Jan-2010	19-Jan-2010	NJ		19-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives night of vaccine & continued to increase over 3 d.

Other Meds:

Lab Data: (-)

History: (-)

Prex Illness: (-)

Prex Vax Illns:

Vaers Id: **377273-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Jan-2010	13-Jan-2010	0	18-Jan-2010	19-Jan-2010	UT		02-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B036BA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1497X	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2659AA	0	Right arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Chest X-ray normal, Chest pain, Decreased appetite, Dehydration, Dizziness, Dyspnoea, Malaise, Myalgia, Nausea, Orthostatic hypotension, Pyrexia

Symptom Text: Myalgias, weakness, chest pain, dyspnea, malaise, anorexia, nausea and dizziness; began a few hours after shots given. Patient evaluated and admitted to hospital next day when patients family called to report symptoms. Dr believes related to Gardasil/HPV vaccine. ```PCP notes received 01/21/10 for DOS 01/13/10. Pt presented for a routine physical and received vaccination. Few hours later, Pt had myalgias, weakness and HA, chest pain, dyspnea, malaise, anorexia, nausea, dizziness and fever. DX: acute febrile illness with transient hypotension, chest pain, and diffuse myalgias. Pt admitted to hospital the next day. ```H&P and DC summary received 01/21/10 for DOS 01/14/10-01/15/10. DX: acute febrile illness with transient hypotension, chest pain, dyspnea and weakness likely sec to HPV vaccination. Pt c/o orthostatic potension, dyspnea, malaise, weakness and fever. Pt found with Vit D deficiency. Tx: hydration and analegsics. Pt instructed to defer HPV vaccination as this was likely the cause of severe symptoms. Pt rehydrated and condition improved. Pt discharged home.

Other Meds: Multivitamin

Lab Data: Chest x-ray, blood draws; D-dimer; Sed Rate; Lactate; CRP; Mono-spot; CMP; CT of chest; D-dimer elevated; More info attached. ```Labs and DX studies: CXR negative. BP 110/58 mmHg.

History: ```PMH: dizziness, ankle weakness. Allergies: NKDA.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 377284-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Oct-2009	30-Oct-2009	3	18-Jan-2010	19-Jan-2010	FR	WAES0912USA00286	19-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Fall, Head injury, Loss of consciousness

Symptom Text: It was reported by a healthcare professional via foreign company representative on 18-NOV-2009. This case in linked with non-serious case (corrected on 13-JAN-2010) E2009-10746. (same reporter, different product, corrected on 13-JAN-2010), that a female patient had received a first dose of GARDASIL (batch number not reported) on an unspecified date. Three days after vaccination, the patient fell off her bicycle and lost consciousness. She could not remember anything and was not able to say whether she had fallen accidentally or had a malaise. Neurological test were performed but the result were not reported. The reporting investigator physician believes there was no connection between the event and the vaccination. Follow up information received from the Health Authorities on 07-JAN-2010: Case upgraded to serious according to the Foreign Health Authorities. The patient was 14 years old. She had received the first dose of GARDASIL on 27-OCT-2009, i,e 3 days after vaccination, she experienced loss of consciousness and cranial trauma as she fell from her bike. However, the patient presented with a full amnesia of the event and consequently could not tell whether she first fell from her bike and experienced loss of consciousness and cranial trauma, or if she lost consciousness as she was riding her bicycle and then experienced a cranial trauma. There was no witness of this event. Malaise was no longer mentioned. Cardiological and neurological examinations were normal. At the time of reporting, the outcome was not provided. To be noted that the linked cases was non-serious and concerned a different product, as corrected in the introductory sentence. Other business partner's numbers included: E2009-10741. No further information is available.

Other Meds: Unknown

Lab Data: Neurological examination, 30?Oct09, normal; Cardiovascular evaluation, 30?Oct09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **377318-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Dec-2009	10-Dec-2009	1	19-Jan-2010	20-Jan-2010	OH		20-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood glucose normal, Dizziness

Symptom Text: Dizziness for 1 month following GARDASIL #2.

Other Meds:

Lab Data: Blood glucose; Hemoglobin, normal

History:

Prex Illness:

Prex Vax Illns: Local rash following vaccine~Meningococcal (Menactra)~1~0.00~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Oct-2009	08-Nov-2009	27	19-Jan-2010	20-Jan-2010	MO		16-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Headache, Nausea, Pain in extremity

Symptom Text: Bilateral upper arm pain(non specific), leg, and knee pain, nausea, headache. All symptoms persist since shortly after vaccine.

Other Meds: none

Lab Data: BCB - nl; ESR - l

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377327-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Jan-2010	10-Jan-2010	1	19-Jan-2010	19-Jan-2010	ID		19-Jan-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU	SANOFI PASTEUR	U3273AA	1	Left arm	Unknown	
HPV4	MERCK & CO. INC.	1353P	3	Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	12578	2	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U2990AA	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscle spasms

Symptom Text: Within 24 hours of vaccine administration patient awoke with severe neck muscle spasm, relieved by pain meds.

Other Meds: None

Lab Data: X-ray

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377419-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Jan-2010	19-Jan-2010	0	19-Jan-2010	20-Jan-2010	VA		20-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X		Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0739Y		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3091AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Child after 15 minutes of receiving immunization c/o headaches (in between eyes). BP: 121/82, reexamined child, fundi disc sharp, BV normal, child received a popsicle-> and waited=15 minutes later. BP: 110/69, P 80: Headache resolving, TYLENOL 1 gram given PO after eating lunch.

Other Meds: None

Lab Data: None

History: None

Prex Illness: Adenitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377426-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	14-Jan-2010	15-Jan-2010	1	19-Jan-2010	20-Jan-2010	MT		20-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash erythematous

Symptom Text: generalized red, raised bumps. Not itchy; no SOB

Other Meds: Ortho Novum 1/35

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377435-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Jan-2010	19-Jan-2010	0	19-Jan-2010	20-Jan-2010	OR		20-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U3350AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0249Y	2	Left arm	Unknown	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500824P		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus

Symptom Text: Facial itching and redness within 10 minutes of receiving 3 vaccines.

Other Meds:

Lab Data:

History: Mild chronic eczema

Prex Illness: None

Prex Vax Illns:

Vaers Id: **377512-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Nov-2009	12-Nov-2009	0	20-Jan-2010	21-Jan-2010	FL	WAES1001USA00989	21-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y		Unknown	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Drug exposure during pregnancy, Induced labour, Pre-eclampsia

Symptom Text: Information has been received from a physician concerning a 17 year old female patient with no pertinent medical history and no known allergies who on 12-NOV-2009 was vaccinated with a 0.5ml IM dose of GARDASIL (Lot# 663453/0249Y) and a meningitis vaccine (manufacturer unspecified) while pregnant (third trimester). There was no concomitant medication. On 12-NOV-2009 an ultrasound test was performed which showed the patient was 31 weeks of gestation. Her due date was 13-DEC-2009. Subsequently the patient experienced preeclampsia and was admitted in the hospital. Labor was induced and the child was healthy. At the time of the report the patient had recovered. The reporting physician considered preeclampsia to be immediately life-threatening. A lot check has been initiated. Additional information has been requested.

Other Meds:

Lab Data: Ultrasound, 11/12/09, 31 weeks gestation

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377515-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
46.0	F	21-Dec-2009	21-Dec-2009	0	20-Jan-2010	21-Jan-2010	FR	WAES1001USA00922	21-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest discomfort, Dyspnoea, Head discomfort, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a 46 year old female healthy housewife with hypothyroidism, joint pain, and asthma who on 21-OCT-2009 was vaccinated with the first dose of GARDASIL. On 21-DEC-2009 the patient was vaccinated intramuscularly with the second dose of GARDASIL (lot# 0747X, batch# NJ22330) at 9:30 AM. Concomitant therapy included some unspecified medication for hypothyroid and some unspecified home medication for joint pain and past history of asthma. On 21-DEC-2009, the patient experienced breathlessness, chest discomfort and heampussui in the head at 9:40 AM and was hospitalized for 1 day. Urine test for microscopic observation (results not reported) and test (not readable) reported as normal were performed. Subsequently, on unknown date the patient recovered. Additional information is not available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 21?dec09, test (not readable) reported as normal; urinalysis, 21?Dec09, urine test for microscopic observation reported as normal

History:

Prex Illness: Hypothyroidism; Arthralgia; Asthma

Prex Vax Illns:

Vaers Id: **377519-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Jan-2010	11-Jan-2010	0	20-Jan-2010	21-Jan-2010	FL	WAES1001USA00988	21-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1131X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood test, Condition aggravated, Convulsion, Grand mal convulsion, Hyperhidrosis, Hypotonia, Loss of consciousness, Neurological examination normal, Pallor, Syncope

Symptom Text: Information has been received from an advanced registered nurse practitioner concerning an 18 year old female patient with history of fainted in the past after seeing needles who on 11-JAN-2010 was vaccinated with a first 0.5 ml dose of GARDASIL. The nurse practitioner reported that "as she was withdrawing the needle from the patient's arm, she went limp and went back on exam table, then seized loss of consciousness, came to conscious and reported seizure activity. She left in ambulance to a hospital (stayed in hospital was unknown) and she was stable. Neurological evaluation was negative. Follow up information has been received from an advanced registered nurse practitioner concerning the patient on 11-JAN-2009 was vaccinated with the first dose of GARDASIL (Lot # 661954/1131X), 0.5 ml, IM. The patient did not received any concomitant vaccinations at that time. When the registered nurse withdrew the GARDASIL needle from the patient. the patient became limp and had a tonic- clonic seizure with loss of consciousness that lasted about 60 seconds. The patient regained consciousness and had another tonic- clonic seizure with loss of consciousness that lasted about 40 seconds. The patient regained consciousness and was pale and diaphoretic. Oxygen was administered and the patient's blood pressure was 80/40. The paramedics were called to the office and the patient was transported to the Emergency Room (ER) at a hospital. At the time the patient refused intravenous (IV) therapy. Blood laboratory tests were drawn in the ER and the patient fainted. The patient regained consciousness and recovered. The patient was not admitted to the hospital; she was kept in the hospital for one hour and was sent home. On 12-JAN-2010 during a conversation with the registered nurse the patient reported that she had recovered. The patient had a scheduled appointment to see the advanced registered nurse practitioner on 14-JAN-2009 for routine physical. Upon internal review tonic-clonic seizure was considered an other important medical event.

Other Meds: Unknown

Lab Data: blood pressure, 01/11/10, 80/40 mmHg

History: Syncope

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377617-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Jan-2010	20-Jan-2010	0	20-Jan-2010	20-Jan-2010	NY		21-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1316Y	2	Left arm	Intramuscular	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500852P	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pallor, Unresponsive to stimuli, Vomiting

Symptom Text: Brief period of unresponsiveness about 75 seconds right after receiving nasal H1N1 (had received HPV several seconds previously), palor and nausea upon spontaneous recovery, followed by vomiting after drinking water

Other Meds:

Lab Data: None needed

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: 377649-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Mar-2008	12-Jul-2008	107	20-Jan-2010	21-Jan-2010	MD		19-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	15224	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Crying, Dizziness, Grand mal convulsion, Paraesthesia, Tongue biting, Unresponsive to stimuli

Symptom Text: generalized seizure - neurologist consulted - MRI WNL, EEG with generalized spike waves, and placed on Lamictal ```MR received 01/21/10, 01/22/10 for DOS 07/12/08. Pt presented with altered counsciousness. Pt fell in shower and appeared confused, did not remember event, bite tongue, crying. Pt seen in ED and all systems negative upon review. On 08/13/08, Neurologist reported Pt had a single, unprovoked seizure and did not have any sz reoccurrences. Neuro exam negative. Pt seen again on 10/27/08 and EEG confirmed sz. Impression: new onset sz. Lamictal started. On 05/08/09 and 08/24/09, Pt had another sz episode (grand mal sz) and Lamictal increased. On 10/01/09, Pt seen by neurologist and c/o HA. Neurologist decided to wean Pt off Lamictal and Topamax started. 11/17/09, Pt had another sz episode. EEG abnormal. 12/14/09, Pt reported paresthesia, lightheadedness, nonresponsive. Topamax stopped, Vimpat started. 12/22/09, Pt's parent stated that Gardasil may have caused 1-st sz. Neurologist referred Pt to PCP, FDA, manufacturer. 01/06/10, Pt got a second opinion from another specialist and continued on Vimpat and Lamictal.

Other Meds:

Lab Data: MRI WNL, but EEG showed generalized spike-waves, leading to treatment with Lamictal. Other lab tests WNL. ```DX studies: brain MRI and CT negative; EEG abnormal.

History: ```PMH: none; Allergies: Ceclor.

Prex Illness: no

Prex Vax Illns:

Vaers Id: 377657-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	12-Jan-2010	13-Jan-2010	1	21-Jan-2010	21-Jan-2010	CA		17-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1480Y	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Gait disturbance, Joint swelling

Symptom Text: Got the last of the hpv vaccine woke the next day with sore swollen ankles. Got worse went back to the doctor who administered the vaccine and talked to him about this reaction. I got worse to the point where I can hardly walk and am in pain so I went to urgent care. ```1/22/2010 Urgent care clinic visit for 1/20/1010 Dx bilateral ankle pain patient with c/o's bilateral ankle pain and swelling x 1 week, difficult to walk, Rx'd prednisone/vicodin/motrin

Other Meds:

Lab Data: none performed ```1/22/2010 Urgent care clinic visit for 1/20/1010 Dx bilateral ankle pain Labs/Dx studies: none noted

History: no ```1/22/2010 Urgent care clinic visit for 1/20/1010 Dx bilateral ankle pain PMH: None noted Allergies: NKDA

Prex Illness: I got the last of the hpv series of vaccines the next morning I woke up with sore swollen on both feet. My ankles are sore and

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377659-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jan-2010	14-Jan-2010	0	21-Jan-2010	21-Jan-2010	NY		21-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1009Y	1	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	500749P		Unknown	Unknown	
	FLU(H1N1)	SANOFI PASTEUR	UP021AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: C/o left arm-seen by MD 1/15/10 12PM-?possible reaction to FluMist, GARDASIL or H1N1 rec'd. No additional doses at this time, no intervention necessary now.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377680-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Jan-2010	14-Jan-2010	0	21-Jan-2010	21-Jan-2010	ME		21-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB387BA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted after giving vaccinations -approx 5 min after, MA laid her down on table, she came to; MA gave crackers and juice - she felt much better within 5-10 min. Was accompanied by father.

Other Meds: doxycycline 100mg daily

Lab Data: none

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **377699-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Jan-2010	19-Jan-2010	0	21-Jan-2010	21-Jan-2010	MA		21-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Chills, Diarrhoea, Dizziness, Headache, Myalgia, Nausea, Vomiting

Symptom Text: when arrived home after shot given developed headache, nausea, vomiting, abd pain, chills, diarrhea and dizziness. + myalgia in neck. No change in gait, numbness/tingling/neck stiffness

Other Meds:

Lab Data:

History: allergic rhinitis

Prex Illness: no

Prex Vax Illns:

Vaers Id: **377703-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Apr-2008	01-Aug-2008	93	21-Jan-2010	22-Jan-2010	FR	WAES1001USA01332	22-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1147U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Crohns disease, Diarrhoea, Haematochezia, Reaction to previous exposure to any vaccine

Symptom Text: Information has been received from a physician concerning adolescent female patient aged 15 or 16 year old who on 30-APR-2008 was vaccinated with the third dose of GARDASIL (batch number NH06740, lot number 1147U). In August 2008, i.e. four months after vaccination, the patient developed stomach ache. In September 2008, she also presented with repeated diarrhoeas. The patient was hospitalized. Blood was found in her stools. Different examinations were performed (no further specification). The diagnosis of Crohn's disease was established. The patient was treated with PENTASA and corticosteroids. To be noted that after receiving the first dose of GARDASIL, she had experienced in December 2007 malaise, vertigo, nausea, lose of consciousness, cephalgia and hypotension at 10/6. She had been hospitalized. vagal malaise had been diagnosed. She had recovered on an unspecified date. Case linked with serious case E2010-00198 (same reporter, same patient, same product, but different dose and different reaction). The patient had received second dose of GARDASIL in December 2007 and had developed stomach ache which had been treated with SPASFON. At the time of reporting, the patient was doing better but pain still persisted.

Other Meds: Unknown

Lab Data: Unknown

History: Vasovagal reaction; Stomach ache

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377704-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Dec-2008	30-Jan-2009	31	21-Jan-2010	22-Jan-2010	FR	WAES1001USA01337	03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1050U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Henoch-Schonlein purpura

Symptom Text: Information has been received from a gynaecologist concerning a 14 year old healthy female who on 30-DEC-2008 was vaccinated with the first dose of GARDASIL (lot #1050U, batch # NH32130, site and route not reported). Four weeks after vaccination (end of January 2009) the patient developed schoenlein-henoch purpura. The patient was treated with prednisolone and recovered completely within 2 weeks. The reporter assessed the relation to the vaccine was possible. Upon internal review, schoenlein-henoch purpura was considered to be an other important medical event. Case is closed. Other business partner numbers included E2010-00109.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **377705-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Nov-2009	24-Nov-2009	21	21-Jan-2010	22-Jan-2010	FR	WAES1001USA01366	22-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1695U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Appendicectomy, Central nervous system lesion, Encephalomyelitis, Hemiplegia, Laparoscopic surgery, Lumbar puncture abnormal, Urinary retention

Symptom Text: Information has been received from a neurologist concerning a 15 year old female patient who on 16-APR-2009 and on 16-JUN-2009 was vaccinated with the first dose (lot# 1477U, batch# NH25390) and second dose (lot# 1400U, batch# NH38400) of GARDASIL which were well tolerated. On 03-NOV-2009, the patient was vaccinated with the third dose of GARDASIL (lot# 1695U, batch# NH25730) (injection route and site not reported). About three weeks post vaccination, the patient underwent a laparoscopic appendectomy. One week later, that is about four weeks post vaccination, the patient developed hemiplegia and urine retention. Initially suspicion of GUILLAIN-BARRE syndrome was raised. The patient was hospitalized in a neurological department for clarification. Several examinations were carried out including MRI which showed active inflammatory lesions in spinal cord and brain. All virological serologies (not otherwise specified) showed negative results. Lumbar puncture showed increased cells at the beginning of hospitalization, afterwards results normalized. Diagnosis of encephalomyelitis was established. The patient was discharged on 13-JAN-2010 in a good general condition but with slight signs of hemiplegia in both hips. The hospital report was requested. Other business partner number included: E2010-00173. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, active inflammatory lesions in spinal cord and brain.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377729-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Jan-2010	18-Jan-2010	0	21-Jan-2010	21-Jan-2010	FL		22-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1317Y	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1110Y	1	Right arm	Subcutaneously	
	HEPA	MERCK & CO. INC.	1100Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Rash macular, Rash pruritic, Tenderness

Symptom Text: Noted an itchy rash R arm soon after VARIVAX given has not changed in size. No fever or pain; has a non indurated mildly tender warm blanching erythematous macule R arm 5 cm x 4 cm.

Other Meds: SYMBICORT

Lab Data:

History: Asthma; Blind L eye

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377732-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		21-Jan-2010	22-Jan-2010	FR	B0626303A	22-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHAB115A	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Loss of consciousness, Vision blurred

Symptom Text: This case was reported by a pharmacist (subject's mother) and described the occurrence of loss of consciousness in a 11-year-old female subject who was vaccinated with TWINRIX (GlaxoSmithKline), (non-gsk) GARDASIL. On an unspecified date the subject received 2nd dose of TWINRIX (unknown), 2nd dose of GARDASIL. At an unspecified time after vaccination with GARDASIL and TWINRIX, the subject experienced loss of consciousness, blurred vision and headache. This case was assessed as medically serious by GSK. At the time of reporting the headache was unresolved. No further information was expected, therefore this case has been closed.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377758-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Jan-2010	20-Jan-2010	0	21-Jan-2010	22-Jan-2010	CA		22-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1108Y	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF551AA	0	Left arm	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	U2929AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1013Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Tremor

Symptom Text: Patient c/o dizziness, cooled pale, shaking. VS take 127/77- P.92 Resp 24 closely monitored in ER. Returned after few minutes, MD notified.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377776-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Jan-2010	21-Jan-2010	0	21-Jan-2010	22-Jan-2010	NY		22-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: headache

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377782-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	21-Jan-2010	21-Jan-2010	0	21-Jan-2010	22-Jan-2010	NY		22-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Nausea

Symptom Text: Nausea and dizziness began approximately 45 minutes following vaccine administered at 11:40 a.m. at 3 p.m. I began experiencing moderate abdominal cramping pain. It is currently 5 pm and the pain has not subsided.

Other Meds:

Lab Data:

History: Mild food allergy to melons

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377800-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Aug-2007	11-Sep-2007	29	21-Jan-2010	22-Jan-2010	IN		11-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Acute stress disorder, Conversion disorder, Crying, Dizziness, Dyskinesia, Fall, Hypoaesthesia, Loss of consciousness, Malaise, Migraine, Mydriasis, Panic disorder, Restlessness, Syncope, Tremor

Symptom Text: Three weeks after Taylor's first Gardasil shot Taylor started having tremors and shaking in her legs. On 9/11 the school called. she was shaking violently all over and was crying because she couldn't stop. We took her to the doctor who checked for low blood pressure, low blood sugar and a few other tests. After the second and third shots she got worse. She started getting dizzy and many times fainting and having seizures. She even started wandering with pupils fully dialated and wasn't "there". Her legs would often go numb and she has had many migraine headaches that would last as long as a week. Also stomach pains and sickness. Her seizures have lasted up to 45 minutes and she is unconsious the entire time. She has had at least 90 episodes! ```1/25/10 Received PCP, Psych & multiple Neuro consults (last 6/10) medical records FINAL DX: non-epileptic seizure-like activity; pseudoseizures; acute stress disorder; conversion disorder; panic disorder w/o agoraphobia; migraine HAs. ```1/25/10 Received hospital medical records for 5/12-13/09. Records reveal patient experienced episodes of dizziness, falls w/jerking movements since beginning 9/2007. Not epileptic, possibly anxiety related. Tx w/meds & counseling which started 10/08. Initially improved then recurred & increased in frequency. Sent by psychiatrist for repeat 24-hour video EEG on 5/12/09.

Other Meds:

Lab Data: Taylor has had multiple tests. EEG's EKG's, full blood work, MRI's, and a Video EEG. CAT scan. All came back normal. Dupont Hospital, Fort Wayne Fort Wayne Neurological Center Lutheran Hospital Fort Wayne Fort Wayne Pediatrics ```1/25/

History: No ```1/25/10 Received medical records w/PMH: PE tubes in infancy. Allergy: Sulfa. Family hx: intention tremors, migraine HAs

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Jan-2010	21-Jan-2010	0	22-Jan-2010	22-Jan-2010	CA		22-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypoacusis, Syncope

Symptom Text: Approx. 5 minutes after administration of Gardasil vaccine, patient left doctors office with her mom, she suddently said I feel everywhere is white then she felt that she is not hearing anything, she said I feel dizzy and then she fainted for about 5 seconds. Her mom held her and avoided her collapse.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377841-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Jan-2010	22-Jan-2010	2	22-Jan-2010	22-Jan-2010	WI		22-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypotension, Loss of consciousness, Presyncope

Symptom Text: Patient recieved #2 of #3 HPV vaccine and within 3 minutes, had a vasovagal reaction. She lost conciousness and was lowered to the floor. Patient became concious about 30 seconds later and was having difficulty responding. Her legs were elevated and a cold pack was applied to her forehead. Her blood pressure was low and the Provider felt that she needed IV fluids and was transferred to the Emergency Department. She was discharged the same day in satisfactory condition.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377843-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	15-Nov-2009	15-Nov-2009	0	22-Jan-2010	25-Jan-2010	FR	WAES1001CAN00160	25-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a nurse concerning a female who on approximately 15-NOV-2009 was vaccinated with the first dose of GARDASIL, lot # not available. On approximately 15-NOV-2009, two hours after receiving first dose, the patient experienced numbness and tingling in one toe which lasted one week. It was reported that there was no known injury to the toe. Subsequently, the patient recovered from numbness and tingling in one toe. Numbness and tingling in one toe was determined to be an important medical event based on foreign agency requirements. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377866-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Dec-2009	24-Dec-2009	2	22-Jan-2010	22-Jan-2010	IN		22-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1332Y	1	Left arm	Unknown	
	FLU(H1N1)	SANOFI PASTEUR	UP032AA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Injection site pain, Injection site papule, Vomiting

Symptom Text: 12-22-09 Complained arm left deltoid pain and bump. 12-24-09 Vomit and abdominal pain. ER visit 12/24/09. IVF and IV pain med. 1-17-10 Vomit and abdominal pain.

Other Meds: Alesse for menorhapn.

Lab Data: CT abdomen; U/S abd and peins

History: PCN for allergies

Prex Illness: None

Prex Vax Illns:

Vaers Id: **377874-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	05-Feb-2008	05-Feb-2008	0	22-Jan-2010	22-Jan-2010	MA		23-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abnormal behaviour, Affective disorder, Mood swings, Oppositional defiant disorder, Suicidal ideation

Symptom Text: Development behavioral changes, mood swings which mother believes began after 1st HPV, given 2/5/08. Ultimately hospitalized and diagnosed with Oppositional Defiant Disorder and Mood Disorder. ```MR received 02/03/10 for DOS 02/06/09-12/07/09. Pt had a routine visit to PCP on 02/06/09 and everything was normal. On 12/07/09, Pt presented with behavior changes, tantrums, police interventions, suicide threats. Pt admitted to group home on 12/21/09 after suicide threats. Pt underwent psychiatric evaluation and counseling. DX: ODD and Mood Disorder. Tx: Risperidal. 01/13/10, Pt's mother reported that Pt had behavior problems since receiving HPV vaccine.

Other Meds: None

Lab Data: None

History: ```PMH: L radial neck greenstick fx, Allergies: NKDA.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **377929-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Jan-2010	12-Jan-2010	1	22-Jan-2010	25-Jan-2010	WA		25-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1313X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature normal, Erythema, Induration, Injection site pain, Injection site warmth

Symptom Text: Large red induration. Tender warm to touch at site. Low grade temp 99.3 (tympanic).

Other Meds: ocella

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378037-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		25-Jan-2010	26-Jan-2010	--		26-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Anxiety, Convulsion, Headache, Impaired work ability

Symptom Text: My granddaughter had the 3 shot series of GARDASIL approximately 2-3 yrs ago. She was a perfectly healthy normal teenager. Then you had the GARDASIL. Since then she continues to suffer from debilitating headaches and has seizures - she had been seen by a neurologist and there tests show no signs of Epilepsy, just some sort of "seizure disorder". This has made a drastic change in her lifestyle. She no longer goes out with her friends for fear of having a seizure, finds it impossible to hold a job because of these problems, and lives with constant anxiety over what will happen next. Also, she has a younger sister who had two of the shots and ever since has had problems with dizziness and blacking out. These were both perfectly healthy young girls before these shots.

Other Meds:

Lab Data: Patient has been in and out of the hospital for the last couple of years since having the GARDASIL shots. I would have to contact her doctor or hospital for exact dates.

History: The only pre-existing medical condition was Asthma, she has had no pregnancies, does not smoke or use alcohol or illegal drugs.

Prex Illness:

Prex Vax Illns:

Vaers Id: **378041-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Jan-2010	20-Jan-2010	0	25-Jan-2010	25-Jan-2010	TX		25-Jan-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500870P	0	Unknown	Unknown	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB555AA	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1353Y	1	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1160Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient received vaccines; shortly after ~2-5 mins. fainted to floor; immediately arousable; no injury; patient laying supine with legs elevated over heart level; patient oriented x4 reports did not have breakfast. Received graham crackers with peanut butter observed for ~20 minutes; Vital Signs stable; Neuro checks WNL; reports no pain; walked out with steady gait with Mother of Child.

Other Meds:

Lab Data:

History: None Noted Per Screening Questionnaire per Mother of Child

Prex Illness: No

Prex Vax Illns:

Vaers Id: **378095-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		25-Jan-2010	26-Jan-2010	--	WAES1001USA01969	26-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Antibody test, Blindness, Borrelia burgdorferi serology, Chest X-ray, Chorioretinal scar, Choroiditis, Differential white blood cell count, Full blood count, Fundoscopy abnormal, Inflammation, Retinal pigment epitheliopathy, Syphilis test, Tuberculin test, Visual acuity reduced

Symptom Text: It was reported in a published article, title as stated above that a 17 year old female who was vaccinated with GARDASIL. The patient was referred for new onset vision loss in both eyes 3 weeks after being vaccine. A standard dose of 0.5 ml was injected intramuscularly into the left deltoid without any resulting skin reaction. Her medical history was significant for depression treated with quetiapine. Three weeks following vaccination, she developed painless vision loss in the left eye followed 2 days later with painless vision loss of the right eye. The patient denied any viral prodrome. On examination, visual acuity measured 20/60 in the right eye and 20/100 in the left eye. Intraocular pressure measured 14 mm Hg in both eyes, and there was no conjunctival injection, no anterior chamber cells and no anterior vitreous inflammation on dilated fundus exam she was found to have multiple creamy chorioretinal infiltrates in the macula extending into the id-periphery, left eye greater than right. On fluorescein angiography, the lesions demonstrated early hypofluorescence and late hyperfluorescence. Systemic evaluation was within normal limits and included a complete blood count with differential, tuberculin skin test, chest radiograph, lyme titres, rapid plasma regain and fluorescent treponemal antibody. There was no family history of autoimmune disease. The patient was diagnosed as having acute posterior multifocal placoid pigment epitheliopathy (APMPPE) and observed. After 5 days, the patient's vision deteriorated to 20/400 in the right eye and count fingers at six feet in the left eye, and fundus exam demonstrated chorioretinal scarring in the macula with persistent activity of the lesion margins. At this time, because of the scarring, the diagnosis shifted to ampiginous choroiditis, and oral prednisone 1 mg/kg/day was initiated. The prednisone was successfully tapered off within 3 months without recurrence of the choroiditis, but extensive macular scarring remained. The final visual acuity was 20/50 in the right e

Other Meds: Unknown

Lab Data: Visual acuity test, 20/60, in the right eye; visual acuity test, 20/10, in the left eye; intraocular pressure, 14mm, in both eyes; ophthalmic angiography, the lesions demonstrated early hypofluorescence and late hyperfluorescence; visual ac

History: Depression

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378096-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Dec-2009	28-Dec-2009	0	25-Jan-2010	26-Jan-2010	FR	WAES1001USA01761	26-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Syncope

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-022065341) concerning a 14 year old female with no pertinent medical history who on 28-DEC-2009 was vaccinated with a dose of GARDASIL (batch number not reported) by intramuscular route (site of administration not reported). 10 minutes after vaccine administration the patient presented dizziness with loss of consciousness that lasted a few seconds. She recovered spontaneously after attending the primary care center. In the HAs report syncope and faint are the coded adverse events. Case reported as serious by the HA with other medically important condition as criteria. Case is closed. Other business partner numbers include E2010-00275.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378097-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Jan-2010	08-Jan-2010	3	25-Jan-2010	26-Jan-2010	FR	WAES1001TWN00007	26-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	FLU(H1N1)

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Coma, Convulsion, Daydreaming

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 09-MAY-2009, 14-JUL-2009 and 05-JAN-2010 was vaccinated with the first, second and third dose of GARDASIL. The patient did not complain any adverse experienced after the first two doses of GARDASIL vaccinations. On 09-DEC-2009, the patient received H1N1 and she experienced absent mind after the vaccination. On 05-JAN-2010, the patient received the third dose of GARDASIL. On 08-JAN-2010 the patient experienced seizure and then she was hospitalized. The patient was in coma status. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378098-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		25-Jan-2010	26-Jan-2010	TX	WAES1001USA01283	26-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dyskinesia, Immediate post-injection reaction, Laboratory test

Symptom Text: Information has been received from a physician concerning a patient's little sister (age unspecified) with unspecified medical history, drug reactions or allergies, who on an unspecified date was vaccinated with a 0.5 mL dose of GARDASIL (route and lot # unknown). Concomitant medication was unspecified. The physician reported that on an unspecified date, a patient's little sister experienced seizure like activity and jerking for a couple of minutes after receiving GARDASIL. Lab diagnostic studies performed were unspecified. It was unspecified if the patient sought medical attention. At the time of the report the patient's outcome was reported as improved. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **378204-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	23-Oct-2009	23-Oct-2009	0	26-Jan-2010	27-Jan-2010	FL		27-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Hypoaesthesia, Oedema peripheral, Pain in extremity

Symptom Text: Severe pain in left hand - injection in left arm. Swelling - numbness - redness in left hand. Symptoms began evening of injection. Two emergency room visits followed.

Other Meds:

Lab Data: Neurological

History: Pre-menstral Dysphoric Disorder

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378243-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		26-Jan-2010	26-Jan-2010	MI		27-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1100Y	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	2	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	5	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain

Symptom Text: Local reaction - redness, induration, and tenderness at injection site - Both (R) and (L) arms.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: Local reaction~Hep A (no brand name)~UN~0.00~Sibling|Local reaction~Meningococcal (Menactra)~UN~0.00~Sibling

Vaers Id: 378278-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	13-May-2009	13-May-2009	0	26-Jan-2010	27-Jan-2010	--	WAES0905USA01929	27-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Intra-uterine death

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning her daughter, a 24 year old female with a history of ectopic pregnancy one year ago who approximately on 13-NOV-2008 was vaccinated with the first 0.5ml dose of GARDASIL intramuscularly. On 13-MAY-2009, the patient was vaccinated with the third 0.5ml dose of GARDASIL while pregnant. There were no concomitant medication, drug reactions and allergies. The home pregnancy test resulted positive on 14-MAY-2009. The patient's LMP was not reported. The patient had sought unspecified medical attention. Follow-up information has been received from the registered nurse, concerning her daughter, a female patient who smoked but stopped smoking at 6 weeks gestation. It was reported that the date of last menstrual period was 02-APR-2009 and the estimated delivery date was 07-JAN-2010. On 17-MAY-2009, pelvic and abdominal ultrasound was performed. On 17-JUN-2009, pelvic and abdominal ultrasound was performed which showed fetal death. Subsequently, the patient experienced a spontaneous abortion. Upon internal review, spontaneous abortion was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, 06/17/09, pelvic and abdominal: fetal death; beta-human chorionic, 05/14/09, positive

History: Ectopic pregnancy

Prex Illness: Pregnancy NOS (LMP = 4/2/2009); Smoker

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378279-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Jan-2010	13-Jan-2010	0	26-Jan-2010	27-Jan-2010	FR	WAES1001USA01858	27-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, No reaction on previous exposure to drug, Petit mal epilepsy, Syncope, Tonic clonic movements

Symptom Text: Initial information received on 14-JAN-2010 from a company representative. Some information was confirmed afterwards by a physician. Case concerns physician's daughter, a 14 year old female patient who on 13-JAN-2010 was vaccinated with the third dose of GARDASIL (lot number and batch number not reported), site and route of administration not reported. Initial information was given by the company representative on 14-JAN-2010, according him, 15 minutes after vaccine administration the patient suffered syncope, which lasted for one minute, and presented tonic-clonic movements in the right leg. 15-JAN-2010 the health care professional was contacted. According to the physician the event lasted for 1 minute approximately, the patient suffered something like an absence seizure, after the event the patient could not remember what had happened. The patient recovered completely on the same day of vaccine administration (13-JAN-2010). The health care professional considered this adverse event as non-serious. This case was assessed as serious by agency as other medical event (Absence seizure). The patient received the first and second dose of GARDASIL without adverse events (dates, manufacturer, batch number, route and site of administration not reported). Other business partner numbers include E2010-00251. Case is closed. No further information has been given.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 378280-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	13-Oct-2009	16-Oct-2009	3	26-Jan-2010	27-Jan-2010	FR	WAES1001USA01929	27-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Encephalomyelitis, No reaction on previous exposure to drug, Paraesthesia, Paraesthesia oral, Paresis

Symptom Text: Information has been received from a Health authority under local reference number GR20090627 and GR0901454 on 14-JAN-2010. A 27 year old female patient, had received a dose of GARDASIL (batch number and site not reported) via intramuscular route on 13-OCT-2009. On 16-OCT-2009, the patient experienced paresis, facial paraesthesia and circumoral paraesthesia. The patient had a concomitant therapy with estrogen-progestogen contraceptive. The patient was hospitalized for paresis of the left superior limb, with sensation of paralysis of the face (on the left side) and facial paraesthesia appeared 48 hours after the vaccination with GARDASIL vaccine (third injection on 13-OCT-2009). The two previous injections (on 01-APR-2009 and 08-JUN-2009) induced no reaction. To be noted that the patient took POPPER 15 days before (data collected via the family doctor of the patient). An encephalomyelitis was then suspected. The infectious serology (viral, bacterial and parasitic) returned negative for the serum and the CSF. The cytology examination of the CSF didn't highlighted malignant cells. The electrophoresis of the CSF proteins recovered a normal repartition. The rest of the biological examination had no particularity (normal autoimmune workup). On 04-NOV-2009 the symptoms had well regressed. In conclusion, the accountability of GARDASIL was taken in account, without ruling out the responsibility of the POPPER. At the time of reporting, the patient was recovering. The outcome was not reported. The health authorities assessed the causal relationship between the reported reactions and vaccination with GARDASIL vaccine as "doubtful" (C2 S1 I1) according to the foreign method of assessment. Other business partner's numbers included: E2010-00226.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Diagnostic pathological examination, cytology didn't highlighted malignant cells; CSF protein electrophoresis, normal repartition; clinical serology test, negative (viral, bacterial, parasitic)

History: Encephalomyelitis

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378306-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Jan-2010	15-Jan-2010	0	26-Jan-2010	27-Jan-2010	GA		10-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB167BA	2	Right arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB376AA	1	Left arm	Unknown	
IPV	SANOFI PASTEUR	00422A	2	Left arm	Unknown	
MMR	MERCK & CO. INC.	0483Y	2	Left arm	Unknown	
MNQ	SANOFI PASTEUR	3012AA	1	Right arm	Unknown	
TD	MASS. PUB HLTH BIOL LAB	027A	2	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0216Y	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drooling, Hypoventilation, Loss of consciousness, Malaise, Pallor

Symptom Text: Noted in Incident Report - patient sitting up in chair @ 11:40am - approx 15 minutes after vaccination. Stated - did not feel well, noted patient was pale, shallow breathing, drooling at mouth slightly... LOC. Patient placed in Trendlenberg position, O2 applied, V/S taken. See below. EMS called. Patient taken to hospital for f/u.

Other Meds: None

Lab Data: Initial V/S at 11:40am. B/P 91/63, HR-65. 2nd set V/S at 11:54am. B/P 110/68 HR - unreliable, weak, faint. SPO2 - 95%

History: Hx - asthma - parent noted no meds taken

Prex Illness:

Prex Vax Illns:

Vaers Id: 378361-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Aug-2009	09-Sep-2009	9	26-Jan-2010	27-Jan-2010	OH		28-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Abscess, Chest pain, Conversion disorder, Convulsion, Cyanosis, Dizziness, Dyspnoea, Endotracheal intubation, Eye rolling, Fatigue, Head injury, Headache, Hypoaesthesia facial, Hypoaesthesia oral, Incontinence, Iron deficiency anaemia, Joint stiffness, Loss of consciousness, Oxygen saturation decreased, Paralysis, Phonophobia, Photophobia, Resuscitation, Rhinoplasty, Tremor, Unresponsive to stimuli, Vision blurred

Symptom Text: 9/9/90-seizure like activity lasted 20 minutes, taken home from school. 9/14/09-seizure like act.,lasted 40 minutes,taken by squad to ER found out that Hemaglobins were 8.0 and she now had severe iron defiency anemia,and released. 9/21/09-chest pain/ER visit released. 9/22/09 seizure like act. for 2 hrs.-squad to ER and Admitted for 4 days. 10/1/09-seizure like act, lasted 2 1/2 hrs.squad to Er admitted 3 days. 10/2/09-seizure like act.lasted 45 min. in hospital. 10/28/09-seizure like act.-last 3hrs. taken home. 12/27/09-seizure like act,trouble breathing, ER visit released. 1/2/10-seizure like activity, stopped breathing, CPR performed,paralises for 15 minutes, Squad to ER/released. 1/14/10-seizure like act,trouble breathing,tubed because oxygen level below 70%,squad to ER/transported to another hospital admitted and released after 1 day. ``` 1/29, 2/1, 2/4 and 2/11/2010 , MR for admit 9/22-9/25/2009, 10/1-10/3/2009, PCP records from 9/14-1/11/2010, Neuro consult record notes 11/25/2009, OB notes 10/26/2009, ED records for 1/14/2010, Final Impression: Pseudo-seizures/conversion disorder, Lt axilla abscess on 9/22/2009, 10/1/2009 admitted for seizure-like activity, patient has c/o's blurry vision, body shaking, jaw clenching, incontinence, eyes roll back, LOC, cyanosis, tongue and facial numbness, seizures started 8/8/2009 2 days S/P Rhinoplasty (was struck by a softball causing head injury), decreased responsiveness, headaches since head trauma with photo and phonophobia, dizziness, also has c/o's fatigue and abdominal pain Neurology felt all the seizures were not true seizures but pseudoseizures Cardiology felt seizures not cardiac related Hematology: patient found to have iron deficiency anemia started on FeSO4 on 1/14 2010 patient seen for seizure-like activity, 10 episodes since 8/2009, also lt axillary abscess, I&D of abscess done, IV ABX given , Ativan and dilantin for seizure activity and dc'd on po ABX

Other Meds: now after shot- nothing prior Ferrous sulfate 65mg 1x daily Florinef-0.1mg 1x daily vitamin C-1000mg daily

Lab Data: EKG, EEG, vEEG, CT Scan, lots of blood work. ``` 1/29, 2/1, 2/4 and 2/11/2010 , MR for admit 9/22-9/25/2009, 10/1-10/3/2009, PCP records from 9/14-1/11/2010, Neuro consult record notes 11/25/2009, OB notes 10/26/2009, ED records for 1/14

History: allergic to tree pollen. small windpipe. vasovagal syncope. ``` 1/29, 2/1, 2/4 and 2/11/2010 , MR for admit 9/22-9/25/2009, 10/1-10/3/2009, PCP records from 9/14-1/11/2010, Neuro consult record notes 11/25/2009, OB notes 10/26/2009, ED records for 1/14/2010, Final Impression: Pseudo-seizures/conversion disorder, Lt axilla abscess PMH: Vasovagal syncope Allergies: Tree pollen

Prex Illness: none ``` 1/29, 2/1, 2/4 and 2/11/2010 , MR for admit 9/22-9/25/2009, 10/1-10/3/2009, PCP records from 9/14-1/11/2010, Neuro co

Prex Vax Illns:

Vaers Id: **378370-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Jan-2010	Unknown		26-Jan-2010	27-Jan-2010	FL		27-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	3	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: UPON ENTERING IN THE VACCINES THAT WERE ADMINISTERED TODAY, I DISCOVERED THAT THE HPV WAS GIVEN BACK IN DECEMBER OF 2009, WHICH WAS A LITTLE OVER A MONTH AGO, WHICH WAS NOT ENTERED INTO FLORIDA SHOTS, THEREFOR THE VACCINE GIVEN TODAY WAS GIVEN IN ERROR.

Other Meds:

Lab Data:

History: NO PRE EXISITING DISEASES AND OR ALLERGIES TO ANY COMPONENT RRELATED TO THE VACCINE

Prex Illness: NO ILLNESS

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378397-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	26-Jan-2010	26-Jan-2010	0	26-Jan-2010	27-Jan-2010	MA		27-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1317Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Epistaxis, Loss of consciousness, Nausea

Symptom Text: Patient waited 15 minutes after injection. Pt felt nausous. Got up to go to bathroom, passed out, landed on face, stomach. Had bloody nose. Had seizure-like activity. Taken to hospital for evaluation.

Other Meds:

Lab Data:

History: Endometriosis, Myalgia, Arthralgias, Fibromyalgia

Prex Illness: Endometriosis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378425-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Nov-2009	16-Nov-2009	4	27-Jan-2010	27-Jan-2010	MO		27-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Dizziness, Headache, Hypoaesthesia

Symptom Text: Memory loss. R side of body numb. Headache. Dizziness.

Other Meds: MOTRIN; Orthotrycycline

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378444-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	20-Jan-2010	20-Jan-2010	0	27-Jan-2010	27-Jan-2010	WI		27-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1647X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Pain in extremity, Urticaria

Symptom Text: Had 1 hive on right cheek and left arm pain. Began Benadryl at 5:00 PM and continued for 24 hours. Hive resided and no further hives developed. Left arm pain was not as severe as with dose #2. Resolved within 3 days.

Other Meds:

Lab Data:

History: Possible allergy to yeast. Gets hives on face after eating bread. had severe radiating arm pain and limited ROM after #2 dose of HPV.

Prex Illness: No

Prex Vax Illns: severe arm pain~HPV (Gardasil)~2~21.50~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378544-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Jan-2010	23-Jan-2010	3	27-Jan-2010	28-Jan-2010	MA		28-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Claustrophobia, Dyspnoea

Symptom Text: Intermittent SOB and tight chest, no more than 2 minutes, instantly cleared with going outside and getting "fresh air". No residual cough or chest pain between episodes. Getting less frequent with time. Seen in the office on 1/27 and had normal exam. Only one episode on 1/27 and felt more like claustrophobia than SOB.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 378556-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Jan-2010	22-Jan-2010	2	28-Jan-2010	28-Jan-2010	GA		12-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0980Y	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Dizziness, Dyskinesia, Fatigue, Feeling abnormal, Headache, Muscle spasms, Pain, Paraesthesia, Stress, Unresponsive to stimuli, Vaccine positive rechallenge

Symptom Text: Patient started feeling dizzy, having headaches. After that patient started complaining of tirness. Patient had these same reation from previous dignious of HPV it made her start having seizure again. After a couple of day getting injection the patient would start feeling bad and then would start having seizures. ```2/3/10 Neurology Report received for date of service 10/5/09. Dx: Convulsions NEC. C/o pains everywhere, described as electrical sparks but not consistently located anywhere. Pain typically starts in the vertex region then goes to her spinal column. Working dx. of nonepileptic seizures. Having a fair number of events, which may be triggered by stress. A referral to a psychologist is suggested. Pt. is taking Topamax and Diastat is used when seizures occur. Seizures are described as eye fluttering with finger fluttering and body spasms or generalized jerking. Thrashing is also noted. Also c/o worsening occipital shooting pain with tenderness in the occipital regions reminiscent of what can be seen in occipital neuralgic symptoms. Sensory exam and motor exam both normal. Started on Gabapentin. ```2/9/10 Neurology Report received for date of service 3/4/09. Dx: Partial seizures. Experiencing events described as "gets dizzy and then unresponsive." May fall to the ground but does not have tonic clonic activity. Frequency can be a few episodes in a month, then may go a month without any activity. Tapered off meds in 2005-2006 and was seizure free for a year. Seizures reoccured and pt. was placed back on meds. Previous MRI's unremarkable.

Other Meds: Topamax

Lab Data:

History: Epilepsy disorder. ```2/9/10 Neurology Report received for date of service 3/4/09. PMH: Meningitis.

Prex Illness: N/A

Prex Vax Illns: seizures~HPV (Gardasil)~5~17.00~Patient|seizures~HPV (Gardasil)~5~17.00~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378615-2 (S)** **Related reports:** 378615-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	M	27-Jan-2010	27-Jan-2010	0	03-Mar-2010	04-Mar-2010	TX	WAES1002USA03588	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353Y	0	Unknown	Unknown	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	NULL		Unknown	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from an office manager in a physician's office concerning an 11 year old male who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). Concomitant therapy given on the same date included influenza virus A (antigen type unspecified) vaccine (H1N1) (manufacturer unknown), FLUMIST intranasal and TB skin test. Subsequently the patient experienced a seizure. It was reported that the seizure improved with therapy and on an unspecified date the patient recovered. On 24-FEB-2010, follow up information was received from a medical assistant. The patient's name and date of birth were reported. On 27-Jan-2010, the patient was vaccinated with the first dose of GARDASIL (lot number 662765/1353Y). The patient also received concomitant influenza virus A (antigen type unspecified) vaccine (H1N1) (lot number not reported), FLUMIST intranasal (lot number not reported) and TB skin test (Manufacturer and lot number were unknown). After the patient received the vaccinations, he had a seizure that lasted a few seconds. The patient's blood pressure was 92/60. An ambulance took the patient to an emergency room. The medical assistant stated that the patient was kept in hospital for observation. On an unspecified date, the patient had recovered. The medical assistant stated that it was unknown if the patient's seizure was life-threatening. Additional information has been requested.

Other Meds: tuberculin

Lab Data: blood pressure, 01/27/10, 92/60

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	M	16-Dec-2008	26-May-2009	161	28-Jan-2010	29-Jan-2010	TN	WAES0812USA03338B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature baby, Small for dates baby

Symptom Text: Information has been received from a nurse practitioner, for the Pregnancy registry for GARDASIL, concerning a baby boy whose mother was vaccinated with a first 0.5 ml IM dose of GARDASIL on 06-Aug-2008 and on 16-Dec-2008 was vaccinated with a second dose of 16-Dec-2008 (Lot # 659962/1740U). The baby's mother LMP was on 16-NOV-2008. On 26-MAY-2009 the mother delivered a 2 lb baby boy. It is unknown if the baby was given medical attention. At the time of the report, the outcome of the baby was unknown. Upon internal review low birth weight (2 lb) and baby born on week 27 of pregnancy were considered other important medical events. The mother's experience has been captured in WAES# 0812USA03338. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378647-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Dec-2008	26-May-2009	161	28-Jan-2010	29-Jan-2010	TN	WAES0812USA03338	29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Delivery, Drug exposure during pregnancy, Premature labour, Urine human chorionic gonadotropin positive

Symptom Text: Information has been received for the Merck Pregnancy Registry for GARDASIL vaccine from a Nurse Practitioner concerning a 15 year old female with allergy to CECLOR who on 11-AUG-2008 was vaccinated with first dose of GARDASIL vaccine (Lot # not provided), 0.5ml. intramuscularly in deltoid. Concomitant therapy included hormonal contraceptives (unspecified). On 12-DEC-2008 she received second dose of GARDASIL vaccine (Lot # 659962/1740U) 0.5ml, intramuscularly in deltoid and she was pregnant. Her last menstrual period was 16-NOV-2008 and her estimated due date is 22-AUG-2009 and the day of conception was believed to be on 29-NOV-2008. There were laboratory Diagnostic Studies performed: urine pregnancy test positive. The patient sought medical attention in the office. Additional information has been received from Advance Practice Nurse (also reported as Family Nurse Practitioner) who reported that the patient received first dose of GARDASIL vaccine (Lot # not provided), 0.5ml, intramuscularly in left deltoid on 05-AUG-2008. Concomitant therapy included hormonal contraceptives (unspecified) and vitamins (unspecified). Follow up information has been received from the nurse practitioner who indicated that the patient delivered a 2 lb baby boy on 26-MAY-2009 (WAES# 0812USA03338B1). Upon internal review, premature labor was considered an other important medical event. Additional information has been requested.

Other Meds: Hormonal contraceptives; Vitamins (unspecified)

Lab Data:

History: Pregnancy NOS (LMP=11/16/2008) Allergic reaction to antibiotics

Prex Illness: Pregnancy NOS (LMP = 11/16/2008); Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378718-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	25-Jan-2010	25-Jan-2010	0	28-Jan-2010	29-Jan-2010	NY		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB359AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness, Pallor, Syncope

Symptom Text: syncope lasting approx. 5 seconds. Pt became stiff and turned pale.

Other Meds:

Lab Data: EKG normal, cbc norman, bmp and ca and mg all normal

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378739-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Jan-2010	07-Jan-2010	0	29-Jan-2010	29-Jan-2010	CA		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3249AA	6	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3061AA	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Swelling of left deltoid muscle, very red tender, 3.5 x 4.0 cm size.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378758-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Jun-2007	02-Oct-2009	840	29-Jan-2010	29-Jan-2010	MO		29-Jan-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lesion excision

Symptom Text: Despite vaccinations pt. developed a high grade lesion which had to be treated with laser.

Other Meds: BcPS - ESTROSTEP

Lab Data: Cx Biopsy

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **378798-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Sep-2008	10-Oct-2008	10	29-Jan-2010	01-Feb-2010	FR	WAES1001USA02839	01-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1285U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal rigidity, Aphthous stomatitis, Asthenia, Candidiasis, Clostridium difficile colitis, Dark circles under eyes, Dehydration, Diarrhoea haemorrhagic, Dizziness, Dyspnoea, Enterocolitis, Enterocolitis haemorrhagic, Fibrosis, Gastrointestinal tube insertion, General physical health deterioration, Haematochezia, Headache, Lung disorder, Lung infiltration, Mucosal dryness, Oral candidiasis, Pallor, Pneumonia, Pyrexia, Regurgitation, Skin turgor decreased, Stomatitis, Tongue coated, Upper respiratory tract infection, Vasculitis, Visual impairment, Vomiting, Wegeners granulomatosis

Symptom Text: Information has been received from a Health Authority (reference no. PEI2009027719) concerning an adipose 14 year old female patient who on 30-SEP-2008 was vaccinated IM with the first dose of GARDASIL (batch number NH35150, lot number 1285U) into the left deltoid muscle. On 10-OCT-2008, the patient developed bloody diarrhoea for four times per hour during the day and twice an hour per night. The family physician recommended oral rehydration. The oral electrolyte solution was regorged, the patient vomited repeatedly and developed asthenia and dizziness. She was hospitalized on 21-OCT-2008. At time of admission the patient showed a reduced general condition and exsiccosis, decreased skin turgor, dry mucosa, pallor, dark circles under the eyes, abdominal pain and guarding and coated tongue. Lab findings see lab comments. Stool examination revealed Clostridium difficile toxine. Diagnosis of hemorrhagic enteritis, enterocolitis due to clostridium diff. was established and confirmed by abdominal sonography on 22-OCT-2008 and coloscopy on 28-OCT-2008 (distinctive colitis with ulcers by the evidence of Clostridium difficile). Histology showed ulcerous colitis possible evoked by a severe infectious pathogenesis. Colitis ulcerosa was ruled out. Therapy with solutions for parenteral nutrition was started. Additional treatment included METRONIDAZOLE and VANCOMYCIN for clostridium difficile. Oral nutrition was changed to feeding tube and administration of NUTRISON. In the course the patient developed oral and perianal aphthae which was treated with DYNEXAN and oral candidiasis, treated with ANTIMYCOTIC ointment. Both events improved within the course. Despite antibiotic therapy symptoms did not improve. An autoimmune disease was assumed (increased c-ANCA values) and therapy with PREDISOLONE and SOLOFALK was started on 05-NOV-2008. Hereunder diarrhoea and general condition improved quickly. Oral food and fluid intake was possible again. As bloody stools persisted 12-NOV-2008 PREDNISOLONE was reduced. The patient was discharge

Other Meds: Unknown

Lab Data: diagnostic urinalysis test, 21Oct08, pH 5, Ketone ++, Hb +; diagnostic urinalysis test, 12Nov08, without pathological findings; tuberculin skin test, 21Jan09, negative; WBC count, 21Oct08, 13700 /ul; serum C-reactive protein, 21Oct08, 1.7 m

History:

Prex Illness: Obesity

Prex Vax Illns:

Vaers Id: **378799-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Oct-2008	13-Oct-2008	0	29-Jan-2010	01-Feb-2010	--	WAES0812USA03199	01-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Menstruation irregular

Symptom Text: Information has been received from a nurse practitioner for the pregnancy Registry for GARDASIL concerning a 14 year old female patient with hypertension who on 13-OCT-2008 was vaccinated with her first dose of GARDASIL (Lot#660612/0229X) by intramuscular route and a dose of VARIVAX (lot and route not reported). Concomitant therapy included influenza virus vaccine (unspecified) and DTaP (unspecified). On 09-DEC-2008 the patient received her second dose of GARDASIL (Lot# 660612/0229X). As of 15-DEC-2008, the patient was eight weeks pregnant (LMP 20-OCT-2008, EDD 27-JUL-2009). The patient reported no symptoms. Follow up information has been received for a health care professional who clarified the patient's EDD of 27-JUL-2009 from the initial report. 09-DEC-2009, the patient received her second dose of GARDASIL and shortly after that the patient had a miscarriage. It was also reported that the patient had some irregular periods and got pregnant again (WAES# 1001USA03249). The patient did not have any GARDASIL between the pregnancies and will have her third dose when the patient returns to the office and it is confirmed that she is not pregnant. Additional information is not expected.

Other Meds: Diphtheria toxoid (+); influenza virus vaccine

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 10/20/2008); Hypertension

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **378804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Apr-2009	24-Apr-2009	0	29-Jan-2010	01-Feb-2010	AL	WAES0905USA00014	01-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Blood human chorionic gonadotropin positive, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician concerning an 18 year old female with no known medical history and drugs allergies, who on 24-APR-2009 was vaccinated with a 0.5 ml first dose of GARDASIL, intramuscularly. There was no concomitant medication. On 27-APR-2009 the patient discovery that she was pregnant. No adverse effects reported. The patient had a urine pregnancy test at office that was positive. The pregnancy was confirmed with a blood test. The patient LMP was on 01-APR-2009 and her estimated delivery date will be on 06-JAN-2010. The patient sought medical attention through an office visit. Follow up information received from a physician indicated that the patient was a female. On 09-MAY-2009 the patient had an elective termination of her pregnancy. It was unknown if the products of conception were examined or if the fetus was normal. The patient's outcome was unknown. Upon internal review elective termination was determined to be another important medical event. No further information is available.

Other Meds: None

Lab Data: Diagnostic laboratory, confirmed pregnancy; urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 4/1/2009)

Prex Vax Illns:

Vaers Id: **378805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Dec-2008	17-Dec-2009	371	29-Jan-2010	01-Feb-2010	NY	WAES1001USA02981	01-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a physician for the Pregnancy Registry for GARDASIL, concerning a 17 year old female with a medical history of vaccine exposure to pregnancy (WAES #0901USA01198) who on 11-DEC-2008 was vaccinated with one dose of GARDASIL (lot # 660391/0063X) IM in her deltoid. After the vaccine exposure to the initial pregnancy, the patient transferred from the physician's care another location. The physician reported that according to social workers at this agency, the patient delivered on 17-DEC-2009, which was three months early from her due date. The date of LMP was determined to be in June 2009 and EDD was approximately 17-MAR-2010. The physician thought this pregnancy was a different pregnancy from the initial one reported given the dating conflict. The physician added that the mother tested positive for marijuana at that time, and that "there were a lot of other things going on" with this young mother. The physician did not have information on the health and outcome of the baby. Upon internal review, premature labour was considered to be an other important medical event. The baby's experience has been captured in WAES #1001USA02981B1. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory, positive to marijuana

History: Vaccine exposure during pregnancy

Prex Illness:

Prex Vax Illns:

Vaers Id: **378806-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	U	11-Dec-2008	17-Dec-2009	371	29-Jan-2010	01-Feb-2010	NY	WAES1001USA02981B1	17-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature baby

Symptom Text: Information has been received from a physician for the Pregnancy Registry for GARDASIL, concerning a 17 year old female with a medical history of previous pregnancy (WAES #0901USA01198) who on 11-DEC-2008 was vaccinated with one dose of GARDASIL (lot # 660391/0063X) IM in her deltoid. After the vaccine exposure to the initial pregnancy, the patient transferred from the physician's care to another location. Physician reported that according the social workers at this agency, the patient delivered on 17-DEC-2009, which was three months early from her due date. The physician did not have information on the health and outcome of the baby. Upon internal review, premature baby was considered to be an other important medical event. The mother's experience has been captured in WAES #1001USA02981. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 378807-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	15-Jan-2010	22-Jan-2010	7	29-Jan-2010	01-Feb-2010	MA	WAES1001USA02983	01-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Asthenia, Condition aggravated, Fasciitis, Leukocytoclastic vasculitis, Myalgia, Myofascitis, Pain, Pain in extremity, Rash, Rash macular, Rash pruritic, Tenderness

Symptom Text: Information has been received from a physician concerning a 26 year old female patient with a history of asthma and no drug reactions/allergies, who "last week" on approximately 15-JAN-2010 was vaccinated with the first dose of GARDASIL. Concomitant medications included unspecified birth control. On 22-JAN-2010 the patient had sudden onset and worsening of lower extremity leg pain to a point that the patient would not walk and was admitted to the hospital. Creatine kinase was mildly elevated. Sedimentation rate was performed (results not provided). At the time of the report the patient had not recovered. Follow up information has been received from the physician who reported that the patient's MRI revealed mild bilateral fasciitis of the lower extremities. The patient had elevated ESR and CRP level. The patient was treated with Non-steroidal anti-inflammatory drugs (not specified). The patient was referred to a Rheumatologist, Neurologist and infectious Disease specialist. The physician stated that the patient was able to walk at the time of her discharge from the hospital. "Lower extremity leg pain to a point that the patient would not walk" was considered to be disabling. Additional information has been requested. ```2/1/10 Hospital records received for dates of service 1/20/10 to 1/23/10. Dx: Myofacitis, leukocytoclastic vasculitis. Presents with one day hx. of lower leg rash, pain and weakness. Saw PCP 3 days prior for pruritic vulvar rash. Started on valtrex for possible HSV. In past 24 hrs. developed rash on lower legs, diffuse muscle pain distal to knees and weakness of lower legs. Red macules on proximal inner thighs. Significant bilateral calf tenderness. Dorsiflexion limited by pain. Unable to walk. Discharged after 4 days able to ambulate.

Other Meds: Unknown

Lab Data: Magnetic resonance, mild bilateral fascitis of the lower extremities; Serum creatine kinase, mild elevated; erythrocyte, elevated; serum C-reactive, elevated. ```2/1/10 Hospital records received for dates of service 1/20/10 to 1/23/10.Labs

History: Asthma. ```2/1/10 Hospital records received for dates of service 1/20/10 to 1/23/10. PMH: Asthma.

Prex Illness: Pain in leg

Prex Vax Illns:

Vaers Id: 378882-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	29-Dec-2009	10-Jan-2010	12	31-Jan-2010	01-Feb-2010	OK		01-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1332Y	3	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Cough, Dysphagia, Erythema, Fatigue, Joint swelling, Lethargy, Mobility decreased, Nasal congestion, Nausea, Oedema peripheral, Pain, Pain in extremity, Rash, Rash erythematous, Rash macular, Rash papular, Skin lesion, Tenderness, Vasculitis

Symptom Text: 1.on 1/10 started noticing a rash on her lower legs around her ankles. Kind of just little red dots. 2. The rash kept spreading and getting worse with bigger red blotches all up and down her legs but most heavily concentrated on her lower legs and feet. So, on 1/15 we went to the doctor about the rash, the coughing and an acheness. He didn't know what it was and did some blood work that we wouldn't find out about until Monday (this was Friday). 3. On the evening of 1/17, she had swollen up so bad on her lower legs and ankles that you couldn't see any of her ankle bones, etc. Also was saying that she couldn't hardly swallow so I was concerned that throat was swelling like the legs. So, I took her to the emergency room. They did blood work but said nothing showed up. They started tossing out possible things like lupus and auto-immune disease. I don't think I told the doctors there about her just having had the 3rd gardisell shot. They gave her 60 mg a day of prednisone for 4 days. 4. As of 1/30, she is in severe pain on her lower legs, fatigued, stomach hurts, very nauseous which could be from meds. We have been in repeated contact with the doctor and after several changes in doses of prednisone, she is currently doing 40 mg a day, Lortab as needed for pain and a diuretic. She couldn't go to school Thursday. The days prior she could go but by the end of the day her legs were so swollen and hurt and she could hardly move or use her left one which is the worse. She has now been on the couch or in bed for 3 days straight. ```records received 02/01/2010. ED rec. for 01/18/2010. DX: Skin rash Patient presented with c/o rash and worsening swelling of legs. The rash had a gradual onset and had started a week ago. Examination noted swelling and tenderness in bilateral lower legs. The rash was described as red slightly raised lesions, which did not blanch when touched. The patient was discharged home and given prescriptions for prednisone and Lortab. The patient was counseled to follow-up with PCP in 1-2 days as sym

Other Meds: Singulair advair Proair inhaler for years had taken effexor and Concerta but had stopped both of those in @ May 09

Lab Data: Regular blood works has apparently been clear. ``` 02/01/2010 LABS and DIAGNOSTICS: WBC-10.9 (WNL), HGB-13.6(WNL), HCT-39.0(WNL), Glucose-59 (L), AST-13 (L), Bili tot.-1.2 (H). ``` 02/02/2010 LABS and DIAGNOSTICS: RBC- 4.28 (WNL), HGB-12

History: 1.Exercised induced Asthma 2. kind of routine occuring sinusitis but not at the time the injections were started

Prex Illness: She had an unusual cough, almost asthmatic, that kind of took her breath away. This has started 3 weeks prior. Looking back no

Prex Vax Illns:

Vaers Id: 378921-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Aug-2008	Unknown		01-Feb-2010	01-Feb-2010	MO		18-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279U	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Arthralgia, Autoimmune thyroiditis, Confusional state, Disturbance in attention, Dizziness, Fatigue, Headache, Juvenile arthritis, Menstruation irregular, Mouth ulceration, Pleuritic pain, Rash, Syncope, Temperature regulation disorder, Visual impairment, Weight increased

Symptom Text: Extreme fatigue, joint pain, dizziness and near fainting, rashes, vision disturbences, hair loss and confusion and inability to concentrate. She has seen 7 doctors and been diagnosed with juvenile rheumatoid arthritis, autoimmune thyroiditis and ADD. No medications for these conditions has relieved/cured the symptoms. ```2/3/2010 and 2/17/2010 Pediatric Rheumatology consult records 8/2008-12/2009, Endocrinology consult records, PCP records, Dx Hashimoto's, JRA patient with c/o's chronic fatigue, alopecia, intermittent pruritic rashes, daily oral ulcers, arthralgias, headaches, pleuritic chest pain , temperature intolerance, weight gain and irregular menses sx started 10/2007, tx'd Placquenil, Meloxicam

Other Meds:

Lab Data: ```2/3/2010 and 2/17/2010 Pediatric Rheumatology consult records 8/2008-12/2009, Endocrinology consult records, PCP records, Dx Hashimoto's, JRA Labs: CBC, RA factor, ANA, Anti-DNA, SSA, SSB, Anti-RNP, HLAB27, Anit-CCP AB CRP, UA,

History: None ```2/3/2010 and 2/17/2010 Pediatric Rheumatology consult records 8/2008-12/2009, Endocrinology consult records, PCP records, Dx Hashimoto's, JRA PMH: AutoImmune Thyroiditis (Hashimoto's), ADHD, JRA, scoliosis, Asthma (exercise induced), Dysmenorrhea, Frequent UTI's Fam hx: + for SLE and RA Allergies: NKDA

Prex Illness: None ```2/3/2010 and 2/17/2010 Pediatric Rheumatology consult records 8/2008-12/2009, Endocrinology consult records, PCP record

Prex Vax Illns:

Vaers Id: **378963-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Oct-2008	Unknown		01-Feb-2010	02-Feb-2010	NJ	WAES0810USA01846	02-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a 17 year old female with no pertinent medical history and no drug reactions/allergies who on 09-OCT-2008 was vaccinated with the first dose of GARDASIL, 0.5 milliliter, intramuscular. Concomitant therapy included MENACTRA and tetanus toxoid. The physician reported the patient who received her first dose of GARDASIL was pregnant. The patient said she was not pregnant at the time of the office visit and refused a pregnancy test at that time. The patient's mother called the office later in the day and said the patient was pregnant and her last menstrual period was "2-3 weeks ago" which was on approximately 18-SEP-2008-25-SEP-2008. No adverse effect reported. The patient sought medical attention at office visit. Follow-up information was received from the physician who reported that the teenager and parent decided terminated pregnancy with parental consent. Upon internal review, terminated pregnancy was considered to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 9/18/2008)

Prex Vax Illns:

Vaers Id: **379011-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Nov-2008	12-Nov-2008	1	01-Feb-2010	02-Feb-2010	OH		09-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Anxiety, Asthenia, Dizziness, Feeling abnormal, Headache, Hypersomnia, Influenza like illness, Injection site swelling, Malaise, Muscle twitching, Pain in extremity, Paraesthesia, Syncope

Symptom Text: Flu like symtoms, sore arm, swollen at injection site,tingily feeling all over skin, twitching of hands, feet, arms, legs. Missed lots of school due to NO energy and feeling bad. will somestimes sleep 12 to 20 hours a day. was fainting 10 to 20 times per day for 7 weeks, anxiety at times, some good days some bad days, never can tell when it will hit or how. very healthy before the shot, had slite cat allergies when she was 6. nothing more than that. she is tired of being sick. Dizzy, memorey loss, some head pressure. I know there are more, I'll have to add later. ```2/3/10 MR received for 11/24/08. DX: vax reaction CC: rt arm swollen, pt states vax x2wks ago, parent states pt is tired, not feeling well, diarrhea, nausea.

Other Meds:

Lab Data: Ct head scan, chest x-ray, EKG, heart monitor, blood tests, urine tests. all came back normal.

History: no

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379041-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Jan-2010	29-Jan-2010	0	01-Feb-2010	02-Feb-2010	IN		02-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3016AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Syncope, Tinnitus

Symptom Text: As patient was walking out of building, approximately 15 minutes following vaccination, had sudden onset of ringing of ears, headache and lightheadedness. Did not report this to facility. Headache persisted for 24 hours. On 1/30/10, while kneeling at church, fainted. Mother raised her legs and child recovered quickly. Did not seek medical care.

Other Meds:

Lab Data: no lab work done

History: none reported

Prex Illness: no illnesses reported at time of vaccination

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379044-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	25-Jan-2010	26-Jan-2010	1	01-Feb-2010	02-Feb-2010	TN		02-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3074AA	0	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	C3032AA	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	12034	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	06514	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Rash erythematous

Symptom Text: Small (<5mm) superficial blisters noted at ant upper thighs bilat - 2 on the rt, one of which is unroofed, and one on the left. Not vesicles. Not fluid-filled. Also, on the rt ant upper thigh, multiple (15-20) small avg 6mm diameter blanching erythematous macules - not raised, no blister or skin disruption, not indurated, not painful. No other lesions noted anywhere else on the skin.

Other Meds:

Lab Data:

History: Asthma

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379071-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-Jan-2010	01-Feb-2010	3	02-Feb-2010	02-Feb-2010	CT		02-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0882Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0969Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site infection

Symptom Text: Post vaccine infection, mild, no treatment.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Feb-2010	01-Feb-2010	0	02-Feb-2010	02-Feb-2010	MN		02-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Pallor, Pyrexia, Vomiting

Symptom Text: extremely pale,fever,throwing up,diarhea continued throwing up until 4:00 AM, still has a fever at this time which is 02/02/2010 10:30 AM

Other Meds: desogen(birth control)

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **379130-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Nov-2007	11-Dec-2007	15	02-Feb-2010	03-Feb-2010	--	WAES1001USA02521	03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abnormal behaviour, Anger, Ataxia, Blood product transfusion, Cerebellar syndrome, Depression, Dizziness, Dyskinesia, Eye movement disorder, Gait disturbance, Headache, Hyperglycaemia, Hypokinesia, Mood altered, Muscular weakness, Opsoclonus myoclonus, Reflexes abnormal, Vertigo, Visual impairment

Symptom Text: Information has been received from the author of the literature article title as stated above concerning an 11 year old female with seasonal allergies and mild asthma. Her initial symptoms consisted of a sudden onset of increased "moodiness" causing uncharacteristic anger and depression. These symptoms presented approximately 15 days after receiving her first dose of GARDASIL vaccination on 26-NOV-2007. The uncharacteristic behavior persisted and 1 month after initial mood changes she noted that her "eyes were doing weird things" and she perceived that visual images went "back and forth in circles". The abnormal ocular movements occurred with her eyes closed or open, and could be only minimally suppressed with great effort. There were no other symptoms at this time, however, her eye symptoms became more frequent and troubling to her. She then received the second dose of vaccine 2 months later in addition to MENACTRA vaccine. Four days after these vaccinations she developed noticeable worsening of the eye movements and acute perception of dizziness, which she described as the "room is spinning". This was accompanied by leg weakness requiring assistance to walk and "jumpy arms". Family history revealed a cousin with childhood epilepsy, maternal great aunt with lupus, maternal grandfather died of a rupture aneurysm at age 40, and mother with fibromyalgia, but no movement disorders or paraneoplastic syndromes. Initial examinations revealed conjugate opsoclonus with or without eyelid closure that worsened with attempts to maintain visual fixation. Optic discs were sharp. Cranial nerves were intact. There was mild weakness and impersistence of force in quadriceps, hamstrings, tibials anterior, hip adductors, abductors and iliopsoas. Mycoclonus was noted in upper and lower extremities, but was worse in the upper extremities. Trunk strength was preserved in the supine position with the patient able to perform sit-ups, but weakened with standing. Sensation to all modalities was intact. Myotactic tendon reflexes were brisk

Other Meds:

Lab Data: Physical examination, see narrative; ophthalmological exam, see narrative; diagnostic radiology, multiple imaging studies were normal with no evidence of nebroblastoma, gaglioneuroma or other mass; electroencephalography, normal; serum gluc

History:

Prex Illness: Seasonal allergy; asthma

Prex Vax Illns:

Vaers Id: **379140-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		02-Feb-2010	03-Feb-2010	MO	WAES1001USA03536	04-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Limb malformation, Muscle atrophy, Weight decreased

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the second dose of GARDASIL. The patient was hospitalized with "muscle loss and weight loss" after the second vaccination. It was reported that the patient's "limb were turning inward". It was unknown if the patient was still hospitalized, and the outcome was unknown. The reporter felt that the events were not related to therapy with GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379141-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Nov-2009	Unknown		02-Feb-2010	03-Feb-2010	FR	WAES1001USA03319	03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Sensory disturbance

Symptom Text: Case received from a health professional in a foreign country on 22-JAN-2010. This case is poorly documented. It was reported by a gynaecologist that a previous healthy 15 year old female patient was vaccinated with a third dose of GARDASIL (lot #, injection route and site not reported) on 18-NOV-2009. A few days post vaccination, the patient developed impaired sensibility (not otherwise specified). The reporter assumed that the patient was hospitalized. Lumbar puncture and magnetic resonance imaging (MRI) were carried out and showed no pathological findings. The patient recovered spontaneously within two months. The reporter pointed out that around the time of vaccination the patient restarted medication with hormonal contraceptives. The first and second doses of GARDASIL were well tolerated. Other business partner numbers included E201000512.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Spinal tap, no pathological findings; magnetic resonance imaging, no pathological findings

History:

Prex Illness: Traction

Prex Vax Illns:

Vaers Id: 379142-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Nov-2008	25-Nov-2008	0	02-Feb-2010	03-Feb-2010	NJ	WAES0812USA02180	03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from an office manager, for the GARDASIL a Pregnancy Registry concerning a 16 year old female patient with depression, allergy to penicillin, amoxicillin, BACTRIM, CECLOR, erythromycin and a history of cesarean section performed less than a year ago and kidney stones with her last pregnancy who was vaccinated with the first, second and third dose of GARDASIL, 0.5 mL, intramuscularly, on 20-MAY-2008 (lot # 655604/0052X), 22-JUL-2008 (lot# 0250X) and on 25-NOV-2008 (lot # 0947X) respectively. Concomitant therapy included oral birth control pills (unspecified) and probably ZOLOFT. It was reported that the patient is pregnant. LMP was 31-OCT-2008. EDD was 07-AUG-2009. The patient sought medical attention at the physician's office. Follow up information has been received from an office manager concerning the 16-year-old female patient and revealed that the patient had a termination of pregnancy on 10-JAN-2009 at 10 weeks of gestation. The reporter stated that the patient did not terminate the pregnancy due to the vaccine, rather she had multiple or other personal reasons. The reporter indicated the patient had no problems with the procedure and recovered well. Upon internal review, termination of pregnancy was determined to be an other important medical event. Additional information has been requested.

Other Meds: hormonal contraceptives; ZOLOFT

Lab Data: urine beta-human, pregnant

History: Cesarean section; kidney stone

Prex Illness: Pregnancy NOS (LMP = 10/31/2008) Depression; penicillin allergy; drug hypersensitivity

Prex Vax Illns:

Vaers Id: **379143-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Oct-2009	Unknown		02-Feb-2010	03-Feb-2010	FR	WAES1001USA03586	03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Thrombocytopenia

Symptom Text: Information has been received from a physician concerning a 14-year-old female patient with no history reported who received the second dose of GARDASIL (Batch # not reported) in October 2009. Within an unspecified timeframe, the patient experienced thrombocytopenia and was hospitalized. At the time of reporting the outcome was unknown. Other business partner numbers include E2010-00604. No further information is available.

Other Meds: unknown

Lab Data: unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **379176-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Jan-2010	18-Jan-2010	0	02-Feb-2010	03-Feb-2010	MO		03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0669Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pruritus

Symptom Text: patient c/o itching at injection site, and a lump that has gotten bigger

Other Meds:

Lab Data:

History: Polycystic Kidney Disease

Prex Illness: None known

Prex Vax Illns: Itching~HPV (Gardasil)~1~19.00~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379182-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Nov-2009	19-Jan-2010	61	02-Feb-2010	03-Feb-2010	NY		03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Missed period.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379183-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Feb-2010	02-Feb-2010	0	03-Feb-2010	03-Feb-2010	NC		03-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Hyperhidrosis, Nausea, Pain, Somnolence, Tremor, Vomiting

Symptom Text: My child fell asleep doing homework and was awakened at 6:30 for evening activities. Complained of a headache. Returned early from evening activity complaining of nausea and alternating between chills with shaking and sweats. Episodes of vomiting followed. No fever, no rash. Complained of considerable pain at the time of the injection and immediately following. This submission is approximately eight hours after the injection.

Other Meds: N/A

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **379199-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Jan-2010	19-Jan-2010	0	03-Feb-2010	03-Feb-2010	CO		24-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Nausea

Symptom Text: Light headed - within 15 minutes, nausea, fatigue, headache - persistent. Treated with ZOFRAN.

Other Meds: PROTONIX; SYNTHROID; LEYSTHYOD

Lab Data:

History: Hashimoto thyroiditis; reflux

Prex Illness:

Prex Vax Illns:

Vaers Id: 379213-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Sep-2009	23-Sep-2009	0	03-Feb-2010	04-Feb-2010	FR	WAES0910USA02986	04-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1316U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Arthralgia, General physical health deterioration, No reaction on previous exposure to drug, Ultrasound scan normal

Symptom Text: Information has been received from a health agency (reference number: PEI2009022113) on 20-OCT-2009 concerning a 15 year old female who on 23-SEP-2009 was vaccinated IM with a second dose of with GARDASIL (lot # 1316U, batch # NH38490) in to the deltoid muscle (side not reported). On 23-SEP-2009 the patient experienced pain in both knee. She was hospitalized on an unknown date for unspecified time. Following diagnoses were ruled out: borreliosis, rheumatoid arthritis and an inflammation. Laboratory: CRP, antibodies IgG and IgM (not otherwise specified), rheumatoid factor, ANA (antinuclear antibodies), ANCA (antineutrophile cytoplasmatic antibodies) and AMA (antimitochondrial antibodies) were without pathological findings. The patient recovered within five days on approximately 28-SEP-2009. First vaccination with GARDASIL (lot # 0933U, batch # NH46260) on 20-JUL-2009 was well tolerated. Follow-up information received on 26-JAN-2009 concerning the patient with a medical history of pollinosis and no known rheumatoid diseases in family history. Concomitant therapy included hormonal contraceptives for systemic use. The hospital report was provided by HA. The patient was hospitalized from 25-SEP-2009 to 28-SEP-2009 due to continuous and unbearable pain in both knees. The patient was not able to walk. Pain was defined as 8 in a scale up to 10. Treatment with paracetamol and DOLORMIN did not succeed. The patient was admitted to hospital in reduced general condition. Weight 46 kg and body height 157 cm. Both knees were painful at flexion, left more than right. Internal and external rotation caused also more intense pain at the left knee than at the right one. Laboratory: BSG 5/14 mmn W(no normal range); CRP 0.02 mg/dl (no normal value reported); Antistreptolysin: 102 IU/ml (within the normal range); Anti-Dnase B: 195 IU/ml (normal range: 0-187 IU/ml); Borrelia-IgG and IgM antibodies negative; Rheumatoid factor < 20; ANA 1:<40, negative; AMN 1:<40, negative; cANCA/pANCA 1:<10, negative; Fibrinogen 321 mg/dl (no normal valu

Other Meds: Hormonal contraceptives (unspecified)

Lab Data: serum antimitochondrial antibody test, 20?Sep09, 1:<40, without pathological findings/ negative; serum ANA, 25?Sep09, 1:<40, without pathological findings/negative; serum ANCA, 25?Sep09, 1:<10; serum ANCA, 25?Sep09, 1:<10, without pathologi

History: Pollinosis

Prex Illness:

Prex Vax Illns:

Vaers Id: 379214-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Dec-2009	17-Dec-2009	0	03-Feb-2010	04-Feb-2010	FR	WAES1001USA03453	04-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ02680	0	Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Nausea, Pallor, Swollen tongue

Symptom Text: Information has been received from a agency (report # 087890) via Case Line Listing via CSL as a part of a business agreement concerning a 19 year old female who on 17-DEC-2009 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot# NJ02680; batch# NJ43980). On 17-DEC-2009, less than 1 hour after vaccination, the patient experienced pallor (not severe), nausea (not severe) and tongue swelling non specific (severe). At the time of report the patient had recovered without sequelae. The agency felt that pallor, nausea and tongue swelling non specific were probably related to therapy with GARDASIL. Tongue swelling, non-specific was considered to be life-threatening. The original reporting source was not provided. A lot check has been initiated. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379215-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Jun-2008	19-Nov-2008	147	03-Feb-2010	04-Feb-2010	FR	WAES1001USA03732	04-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Case received from a physician on 21-JAN-2010. A 16-year-old female patient with no relevant medical history received the second dose of GARDASIL (batch number not reported) on 25-JUN-2008. On 19-NOV-2008, she developed a multiple sclerosis. She was treated with corticosteroids in bolus. Her medical condition was stable since. to be noted that there was no familial history of autoimmune disease. "Multiple sclerosis" was considered to be an other important medical event by the reporter. Other business partner numbers included E2010-00536. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379229-1** **Related reports:** 379229-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	02-Feb-2010	02-Feb-2010	0	03-Feb-2010	04-Feb-2010	NC		19-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	1	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	1538Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pain, Pyrexia

Symptom Text: Pt got 2 vaccines 2-2-10, HPV and Hep A. During checkup ran fever most of night. Got as high as 104. Also c/o headache, aches generalized all over.

Other Meds: None

Lab Data: None

History:

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379229-2** **Related reports:** 379229-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Feb-2010	02-Feb-2010	0	09-Feb-2010	11-Feb-2010	NC		22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	1	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	1538Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Patient had 104 fever 2-2-2010 after getting vaccines. Hep A and HPV.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 379241-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	08-Jan-2010	24-Jan-2010	16	03-Feb-2010	04-Feb-2010	PA		06-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Clonus, Confusional state, Headache, Hyperreflexia, Hypoaesthesia, Muscular weakness, Myelitis transverse, Pyrexia, Vision blurred

Symptom Text: weakness, confusion, blurry vision and occipital headache ```2/26/10 DC summary received for dates 1/31/10 to 2/5/10. DX: Transverse myelitis CC: bilat leg weakness/numbness, HA, inability to walk, febrile illness x1week prior to admission. Pt seen in ER with URI symptoms x3days prior. Assessment: densely decreased sensation to mid thighs, hyperflexia, clonus (+) upper extremities. Pt admitted. At time of dc pt improved , dc to rehab facility. At dc pt still with bilat LE hyperflexia and clonus.

Other Meds:

Lab Data: CSF Cx - NG, BCx - NG, CSF 60WBC, 93Lymphs, 0Poly, CSF HSV PCR neg, CSF VZV PCR neg, MRI extensive inflammation of spinal cord from cervical to thoracic ```2/26/10 Diag/Labs: MRI abnormal-excessive cord signal abnormality in most of the c

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379261-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Jan-2010	27-Jan-2010	0	03-Feb-2010	04-Feb-2010	MT		14-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU(H1N1)	SANOFI PASTEUR	UP050AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1316Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: There were no adverse reactions. Patient denied being pregnant or the possibility of being pregnant on 1/27/10. Patient then came into the GYN clinic on 2/02/10 for an exam and had a pregnancy test done and found out she was pregnant. Pt's period was less than 3 days late. ```2/9/10 MR received for date 2/3/10. DX: IUP EDC 10/4/10. OV for prenatal check. no CC at this time.

Other Meds: None

Lab Data: Patient had a positive pregnancy test on 2/2/10.

History: No known drug, food or environmental allergies. ```2/9/10 PMH: smoker

Prex Illness: No illness at the time of vaccination. Patient was asked these questions before any immunization given. 1. Do you have any

Prex Vax Illns: N/A~ ()~~0.00~Patient

Vaers Id: 379292-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Apr-2007	09-Apr-2008	362	03-Feb-2010	04-Feb-2010	NC		23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Back pain, Clumsiness, Computerised tomogram, Dizziness, Dysphagia, Extensor plantar response, Fall, Gait disturbance, Headache, Hypoaesthesia, Loss of consciousness, Muscular weakness, Neuropathy peripheral, Nuclear magnetic resonance imaging, Pain, Pain in extremity, Paraesthesia, Syncope

Symptom Text: Within 1 month after receiving vaccination progressive clumsiness noted with complaints of leg pain with inability to run without falling. Eventually, lost ability to run and only able to participate in some aspects of gym classes. Alternate written assignments had to be done. On April 9,2008 had severe pain to left leg while in bed. While stepping up onto school bus, passed out. Complained of dizziness at that time. pain progressed to right leg that day with tingling and numbness. Taken to ED, CT scan of head and labs done. Referred to neurologist. Many blood tests performed, EMG, nerve conduction studies, MRI's. May 1, 2008 reported right leg pain worsening and now present in right hip and waist. Referred to neurologist due to progressive weakness and right leg lag. Adaptations have had to be made at school through the 504B plan to accomodate for her disabilities. Stairs are very challenging. Swallowing difficulties started within last 3 months. Now seeing neurologist, rheumatologist, endocrinologist to find cause of proximal weakness. Lots of autoimmune studies have been done and repeated. No answer to this problem for a child who was in perfect health prior to this vaccination. Bills are immensely expensive and continue. ```2/4/10 to 2/15/10 MR, hospital records received for dates 6/3/08 to 2/1/10. DX: neuropathy, syncope and collapse, muscle weakness, vitamin D deficiency. CC: 6/08 leg pain and numbness since 4/08. Pt states pain started in left leg, walking made sx worse, starting in pt back then down leg. Then rt leg pain/tingling. Currently localized sharp pain/tingling from knee down to ankle. Pt states now c/o arm weakness x1 month. Pt states has had LOC x4 episodes stating feeling weak and HA prior to LOC episode. Pt states HA are pounding. Babinski sign downgoing bilat, reduced strength noted. PT note: posture unremarkable, good alignment, ROM WNL, decreased balance and weakness.

Other Meds: NONE THAT I CAN RECALL

Lab Data: EMG - showed some disparities right to left. Lupus studies - negative thus far, muscle enzymes - WNL Basic chemistries and hematology testing WNL VIT D level < 6 - started on Vit D supplements - seeing endocrinologist Recent DS DNA posit

History: Allergy to PEARS (RASH)

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **379331-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	21-Dec-2009	21-Dec-2009	0	04-Feb-2010	05-Feb-2010	--	WAES1001USA03663	05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0455Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site rash, Rash pruritic

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female patient with urinary tract infection who on 10-SEP-2009 and 21-DEC-2009 was vaccinated with a first and second dose of GARDASIL, 0.5 mL, IM, (Lot # 0053X and 0455Y respectively). Concomitant medication included unspecified sulfonamide (prescribed by another physician) and birth control therapy unspecified. The patient experienced the onset of an itchy rash at the injection site a few hours after the second dose. The rash spread from the injection site to include the whole arm and chest. The patient was evaluated at an unspecified urgent care facility and was treated with intravenous steroid medications. The patient was prescribed oral steroid medications and BENADRYL. The patient reported to the office by phone on 23-DEC-2009 that she was "greatly improved". The nurse practitioner added that the patient was also taking an unspecified sulfonamide for a urinary tract infection at the time of the onset of the rash. No lab diagnostic studies were performed. At the time of this report, the patient recovered on unspecified date. Upon internal review, pruritic rash treated with IV steroids was considered an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Urinary tract infection

Prex Vax Illns:

Vaers Id: **379332-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Jan-2010	13-Jan-2010	0	04-Feb-2010	05-Feb-2010	FR	WAES1001USA03712	05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Hearing impaired, Syncope

Symptom Text: Information has been received from a foreign Health Authority (ES-AGEMED-922092341) concerning a 15 year old female patient who was administered on 13-JAN-2010 with a dose of GARDASIL (batch # and site not reported), by intramuscular route. It was reported that two minutes after vaccine administration, the patient suffered a faint hitting her forehead. She recovered from syncope although she "heard strange" (as reported). The patient was referred to the hospital for observation (hospital admission not reported). The patient's heart pressure was 100/50, she had 86 bpm and O2 saturation of 96. The outcome is unknown. Case reported as serious per reporter with other medically important condition as criteria. Other business partners included E2010-00635.

Other Meds: Unknown

Lab Data: blood pressure measurement, 100/50; arterial blood O2 saturation, 96; total heartbeat count, 86 bpm

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **379333-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Nov-2009	10-Nov-2009	0	04-Feb-2010	05-Feb-2010	FR	WAES1001USA03714	05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplegia, Pain

Symptom Text: Information has been received from a health authority concerning a 15 year old female who on 10-NOV-2009 was vaccinated with her first dose of GARDASIL intramuscularly (Batch and site of administration not reported). It was reported that on the same day of vaccination, 10-NOV-2009, the patient attended the hospital due to a total paralysis of both lower limbs. The patient was treated with painkillers (as reported) for the strong pain. The patient was hospital admitted (admission and discharged dates not reported), 7 days later the patient recovered. The patient went to the health care center in order to receive the second dose of GARDASIL but it was not administered. Other business partner numbers include E2010-00634. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: 379335-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-May-2009	Unknown		04-Feb-2010	05-Feb-2010	FR	WAES1002USA00089	05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1400U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Influenza like illness, Radiculitis, Sensory disturbance, Troponin increased

Symptom Text: Case received from health authority on 28-JAN-2010 under HA reference no. PEI2009007481. It was reported that a 17-year-old female patient was vaccinated with a first dose of GARDASIL (batch number NH38400, lot# 1400U) IM on 07-MAY-2009, injection route not reported. On an unspecified date in May 2009 the patient developed transient increased troponin P for one day, flu-like symptoms for several days and radiculitis with sensory phenomenon. Suspicion associated generalized imme reaction was established (HA did not code this diagnosis). The patient was hospitalized on an unspecified date. MRI of cervical and thoracic spine, liquor puncture, blood examination and ECG were carried out and supported the diagnosis (not otherwise specified). Myelitis and multiple sclerosis were ruled out. At the time of reporting to HA (30-NOV-2009) the patient had not recovered. Other business partner numbers include E2010-00646. Additional information has been requested.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, ??09, MRI of cervical and thoracic spine; Diagnostic laboratory test, ??09, liquor puncture; Diagnostic laboratory test, ??09, blood examination; Electrocardiogram, ??09

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379347-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-Feb-2010	02-Feb-2010	0	04-Feb-2010	05-Feb-2010	NM		04-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: States that she began experiencing numbness to left forehead and top of head (also tingling sensation) no treatment in ER. 02/04/10 9:20 numbness diminishing. Denies tingling. Feeling better.

Other Meds: None

Lab Data: No blood work done in ER, checked vitals and checked reflexes.

History: No

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379370-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Sep-2009	01-Sep-2009	0	04-Feb-2010	04-Feb-2010	FL		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	U206Y	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0671Y	1	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0848Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Vaccine positive rechallenge

Symptom Text: Patient received 1st dose of HPV on 6/9/09 broke out w/rash. 0 complications pt. recovered. Patient received 2nd dose of HPV on 09-01-09 w/rash more severe occurring within 2 hours of injection D/C series of HPV per Dr.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: 06/09/09~HPV (Gardasil)~1~14.00~Patient

Vaers Id: **379407-1** **Related reports:** 379407-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	25-Jan-2010	26-Jan-2010	1	04-Feb-2010	05-Feb-2010	MI		17-Feb-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0860Y	0	Left arm	Subcutaneously	
TDAP	SANOFI PASTEUR	AC52BA37AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0249Y	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAUB302AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Injection site erythema, Injection site induration, Skin warm

Symptom Text: Within 20-24 hrs after receiving VARICELLA #1 LA.S.O. localized redness, warm, elevated red 30 x 20 mm appeared at vaccine site. Patient/client concerned reaction-encouraged comfort. Next 24 hours-has done nothing so far-Benadryl q 6 hours; Advil, Motrin, q 4-6 hours-Ice to vaccine reddened site-client also stated she felt tired after getting all 4 vaccines. 1/27/10 review of vaccine site 40 x 35 mm. Less induration-larger reddened area but not tender-not sore or bothersome today-ice-Motrin-Benadryl q 4-6 hours last 24 hours-improvement. 1/28/10 arm redness improved.

Other Meds: None

Lab Data: None

History: None

Prex Illness: Past 3 wks upper respiratory no fever

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379420-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	27-Jul-2009	27-Jul-2009	0	04-Feb-2010	04-Feb-2010	WI		04-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Myalgia

Symptom Text: Patient reports feeling muscle aches and fatigue that lasted for 1 week. She had 3 total injections and worsening symptoms with each course. She did not notify our office of complications until today, which is months after her last shot.

Other Meds:

Lab Data: None

History: Allergic to PCN, Amoxicillin, and latex.

Prex Illness: Pt reports being fine at time of injection. She had muscle aches the following 7 days and that worsened with each course of the

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379462-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Feb-2010	01-Feb-2010	0	04-Feb-2010	04-Feb-2010	OK		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pain in extremity

Symptom Text: Nausea 2/1/2010 5:00am 2/2/10 complaining of leg pain/achiness

Other Meds:

Lab Data: n/a

History: No known drug allergies, denies any health problems

Prex Illness: Denies

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379472-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Jan-2010	26-Jan-2010	1	04-Feb-2010	05-Feb-2010	NC		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB342AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0100Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3062AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B047EA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1079Y	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: 3.5cm red raised area at Varicella site. BENADRYL, MOTRIN, Prednisone, ZYRTEC.

Other Meds: None

Lab Data: None

History: Possible latex allergy.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **379503-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	10-Nov-2008	24-Dec-2008	44	04-Feb-2010	05-Feb-2010	WI		23-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dizziness, Eye pain, Fatigue, Feeling abnormal, Headache, Hypoaesthesia, Immune system disorder, Malaise, Night sweats, Oropharyngeal pain, Pain in jaw, Stomatitis, Vision blurred

Symptom Text: Sore throat, night sweats, malaise, severe headaches with no relief of any OTC or prescription medication, dizziness, numbness in extremities, numbness to touch head, bumps in mouth, weakened immune system, chest pain, jaw pain, eye pain, blurred vision, extreme fatigue, brain fog. Symptoms ongoing 14 months post-vaccine.

Other Meds: Continuous Birth Control pill to treat Endometriosis

Lab Data: CT Brain, normal. MRI Brain, left temporal lobe cavernous angioma with previous bleed, Strep, Mono, Thyroid, Lyme, Toxoplasmosis, all other blood work, normal. Esophagram with barrium swallow, normal. Biopsy of nodule in mouth, normal.

History: Endometriosis, Cystitis, HPV

Prex Illness: No.

Prex Vax Illns:

Vaers Id: **379523-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	17-Nov-2009	18-Nov-2009	1	05-Feb-2010	05-Feb-2010	MO		05-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	08164	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Inappropriate schedule of drug administration, Nausea, Urticaria, Vomiting

Symptom Text: Pt had her third GARDISIL 11/17/09. She called the next day to report that on 11/18 AM, she awoke with nausea, soon followed by vomiting. When she got up, she was "lightheaded." Later in the day she developed hives on arms and thighs. Stated that sx are resolving. Told her to take BENADRYL 50 mg now. If hives get worse or throat swells, has difficulty breathing call 911 or have roommate take her to ER.

Other Meds: ZANTAC; LEVORA

Lab Data: none

History: NKDA; allergic to peanuts, grass; asthma; gerd

Prex Illness: no

Prex Vax Illns:

Vaers Id: 379538-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Nov-2007	15-Feb-2008	105	05-Feb-2010	05-Feb-2010	NY		24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	3	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Asthma, Conversion disorder, Dyskinesia, Headache, Loss of consciousness, Menstruation irregular, Migraine, Neurological examination normal, Rash, Sinusitis, Staring, Tilt table test

Symptom Text: Seizures and migraine headaches. ER several times. Hospitalized 4 days for tests - MRI, EEG - diagnosis of seizure disorder - had no problem before GARDASIL. ``` 2/8 and 2/9/2010 MR, DC summary 2/18-2/21/2008 , PCP, Allergist, ENT , Psychologist records 5/2007-7/2009, Final Dx for admit seizures ruled out on 2/15/2010 patient with c/o's jerking movents of the body, LOC, brought to ED and was dc'd with impressiion of pseudoseizure on 2/16/2010 patient felt dizzy and fell and hit her head, brought to ED again and was placed on Keppra but patient continued to have episodes of jerky body movements and staring so on 2/18 was admitted to r/o seizures, was consulted per Neuro, Cardio, Psych consult was negative for conversion d/o, neuro exam noted no deficits, all lab and dx tests were negative except MRI which noted acute sinusitis lt sphenoid and a small mucocele, dc'd to f/up with neurology for Keppra taper, cardiology to check for neurocardiogenic syncope (tilt table test) and with PCP Per MD notes it states patient with multiple ED visits 8/08-4/2009, c/o's headaches, asthma flairs, rash, ruq abd pain. ``` 3/23/2010 OB records 9/21-12/18/2009 dx irregular menses

Other Meds:

Lab Data: MRI and EEG; Blood work ``` 2/8 and 2/9/2010 MR, DC summary 2/18-2/21/2008 , PCP, Allergist, ENT , Psychologist records 5/2007-7/2009, Final Dx for admit seizures ruled out ``` 3/23/2010 OB records 9/21-12/18/2009 dx irregular menses

History: Asthma ``` 2/8 and 2/9/2010 MR, DC summary 2/18-2/21/2008 , PCP, Allergist, ENT , Psychologist records 5/2007-7/2009, Final Dx for admit seizures ruled out ``` 3/23/2010 OB records 9/21-12/18/2009 dx irregular menses PMH: Asthma, GERD, Anemia Allergies: Seasonal, Bactrim, Vancomycin

Prex Illness: ``` 2/8 and 2/9/2010 MR, DC summary 2/18-2/21/2008 , PCP, Allergist, ENT , Psychologist records 5/2007-7/2009, Final Dx for ad

Prex Vax Illns: Seizures~HPV (Gardasil)~3~18.00~Patient|black outs~HPV (Gardasil)~2~14.00~Sibling

Vaers Id: **379546-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Feb-2010	02-Feb-2010	1	05-Feb-2010	05-Feb-2010	--		09-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB3713A	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Fatigue, Myalgia, Pain, Pruritus

Symptom Text: Mon- GARDASIL #3 & HepA #2 shots. Tues- Itching, soreness, ibuprofen 2/200mg, didn't help. Wed- Burning-whole body ached, ibuprofen didn't help. Thurs- Burning, muscle aches, exhausted, will increase to 600mg ibuprofen.

Other Meds: YAZ; SINGULAIR; XOPENEX; FLOVENT

Lab Data: PT evaluation no tests needed @ this time.

History: Asthma

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379564-1** **Related reports:** 379564-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	08-Dec-2008	Unknown		05-Feb-2010	08-Feb-2010	IA	WAES0901USA03985B1	02-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Congenital anomaly, Drug exposure during pregnancy

Symptom Text: Information has been received from Merck Pregnancy Registry for GARDASIL from a Nurse practitioner concerning an 18 year old female with AUGMENTIN allergy and no pertinent medical history who on 06-OCT-2008 was vaccinated with first dose of GARDASIL (Lot # not reported). Concomitant therapy included ZOFRAN. On 08-DEC-2008 she received second dose of GARDASIL (Lot # not reported). When she received second dose of vaccine she was pregnant. Patient had last menstrual period on 13-NOV-2008. Estimated date of delivery was 29-AUG-2009. The nurse practitioner reported that the mother delivered a female on 03-SEP-2009 that has been diagnosed with Laryngomalacia. According to the nurse practitioner, a few days after the birth, the mother brought the baby into the Emergency Room at their hospital with stridor and the baby was transported to a Department of Otolaryngology in a university for care. She said she was told "the baby has extra tissue in the throat", and "along with the stridor which was related to the laryngomalacia, the baby has had reflux and pneumonia at some point too." The nurse practitioner added that it was congenital, but did not state who provided that information. The nurse practitioner added that the baby was gaining weight appropriately. At the time of the report the baby's status was unknown. The infant's laryngomalacia was considered a congenital anomaly. The mother's experience is reported is WAES 0901USA03985. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **379568-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		05-Feb-2010	08-Feb-2010	--	WAES1001USA03872	08-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Laboratory test, Vaccine positive rechallenge

Symptom Text: Information has been received from an office manager who reported that she received an email from a friend concerning a female patient who was vaccinated with the first dose of GARDASIL and about three and a half weeks later began having seizures. Then, the seizures started to intensify after the second and third doses of GARDASIL. It was reported in the email that "for the last two and a half years, the patient had been dealing with seizures. Having never had problems like this, they came out of nowhere". It was reported that the patient had "every test imaginable run, seen various doctors and tried different medicines. There had been times of respite from them, the most recent one lasting 8 months, until 'a couple Fridays ago' when they started back again". It was also reported that "after a lot of research, the patient's parents believed that the root cause of everything was the GARDASIL shot. The patient's episodes began about three and a half weeks after getting the first shot and increased with intensity after getting the second and third ones". The office manager reported that she knew nothing of the patient or situation except through the email which was circulated to her. Upon internal review, seizures were considered an other important medical event. This is one of several reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **379569-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Dec-2008	03-Dec-2008	0	05-Feb-2010	08-Feb-2010	DC	WAES0812USA00560	08-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Beta haemolytic streptococcal infection, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse for the pregnancy registry for GARDASIL concerning a 17 year old female patient with history of anger issues, who on 03-DEC-2008 was vaccinated with the second dose of GARDASIL (Lot 660553/0070X). Concomitant therapy included HAVRIX and hormonal contraceptives (unspecified). Nurse reported that a patient who is now pregnant received her second dose of GARDASIL on 03-DEC-2008. Nurse reported that the patient had received her first dose of GARDASIL over a year ago. A pregnancy test on 22-SEP-2008 was negative and a pregnancy test on 08-OCT-2008 was positive. At the time of the report the patient had a confirmation test done (sonogram). No specific adverse event was reported related to the pregnancy. The patient sought unspecified medical attention. Follow up information has been received from a physician who reported that on 24-JUN-2009 the patient delivered by C-section due to bradycardia a male healthy baby at 41 weeks of gestation. The baby's weigh was 7 pounds 4.6 oz. The physician also reported that on an unknown date the patient experienced a group b streptococcus infection. The patient present status was unknown. Upon internal review C-section due to bradycardia was considered to be other important medical event. Additional information has been requested.

Other Meds: HAVRIX; hormonal contraceptives

Lab Data: ultrasound, confirms 12 weeks gestation; beta-human chorionic, 09/22/08, negative; beta-human chorionic, 10/08/08, positive

History: Anger

Prex Illness:

Prex Vax Illns:

Vaers Id: **379570-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Jul-2009	06-Sep-2009	48	05-Feb-2010	08-Feb-2010	FR	WAES1001USA03763	08-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Death, Drowning, Fall

Symptom Text: Information has been received from from a physician concerning a 12 year old school going girl of class eight of a village. On 20-JUL-2009, the patient received first dose of GARDASIL in the school. During the process of community mobilization for second dose of GARDASIL, the female health worker was informed that on 06-SEP-2009, the patient accidentally fell in open well (granite quarry filled with water), drowned and expired. This event occurred 49 days of receiving first dose of GARDASIL. The female health worker informed the Medical Officer in-charge, which was then communicated to District Immunization Officer. The medical officer in-charge investigated the death and completed first information report and determined that death was not related to the vaccine.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 379571-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Feb-2007	Unknown		05-Feb-2010	08-Feb-2010	FR	WAES1002USA00088	08-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Myositis, No reaction on previous exposure to drug, Visual acuity reduced

Symptom Text: Information has been received from a nurse concerning her 16 year old female daughter with a history of tonsillectomy who was vaccinated with a second dose of GARDASIL (injection site and route not reported) on 26-APR-2007. Concomitant medication included AIDA (hormonal contraceptives). Approx. 5 weeks p.v. the patient experienced relapsing orbital myositis with decreased vision. She was hospitalized twice (exact dates not reported). A focus search was negative, infective causes could not be verified. A "heumatologic disease" was assumed. The first dose GARDASIL, given on 15-FEB-2007, was well tolerated. Despite ongoing symptoms, the third dose was given on 01-OCT-2007. Other business partner's numbers included: E2010-00612. No further information is available.

Other Meds: AIDA

Lab Data: Unknown

History: Tonsillectomy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379572-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		05-Feb-2010	08-Feb-2010	--	WAES1002USA00392	08-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Initial and follow-up information has been received from an office manager who reported that she received an email from a friend concerning a girl who was vaccinated with a dose of GARDASIL and began having seizure episodes within weeks of getting the shot. The office manager reported that she knew nothing of the patient or situation except through the email which was circulated to her. Upon internal review, seizure episodes was considered an other important medical event. Attempts to verify the existence of an identifiable patient have been unsuccessful. This is one of several reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379609-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	M	29-Jan-2010	01-Feb-2010	3	05-Feb-2010	08-Feb-2010	CA		14-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Fatigue, Paraesthesia, Urticaria

Symptom Text: Hives, fatigue, shortness of breath, brief episodes of tingling in feet ``` 2/11 and 2/23/2010 PCP office notes 1/29, 2/3, 2/5 possible vaccine reaction patient with c/o's hives, SOB, eyelids swollen, fatigue, tingling/numbness/feet, neuro exam wnl, no tx noted

Other Meds:

Lab Data: None ``` 2/11 and 2/23/2010 PCP office notes 1/29, 2/3, 2/5 possible vaccine reaction Lab/dx studies: none noted

History: none ``` 2/11 and 2/23/2010 PCP office notes 1/29, 2/3, 2/5 possible vaccine reaction PMH: None noted Allergies: NKDA

Prex Illness: no ``` 2/11 and 2/23/2010 PCP office notes 1/29, 2/3, 2/5 possible vaccine reaction

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379626-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Oct-2009	01-Nov-2009	31	07-Feb-2010	08-Feb-2010	WI		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Alopecia, Axillary mass, Cellulitis, Dysmenorrhoea, Fatigue, Feeling hot, Malaise, Nasopharyngitis, Oropharyngeal pain, Weight decreased

Symptom Text: had flu, nov, jan, hair falling out, run down and tired, armpit lump, feverish, rapid weight loss, bad cramping with periods, colds and sore throat alot, not herself anymore, has alot of cancer systems, abdominal pain,,,her dad took her in against my will... ``` 2/17 and 2/22/2010 Urgent care visit 1/31/2010, Dx Cellulitis lt axillary area patient with c/o's lt axillary "lump" x! week, non-tender, but increasing in size. rx'd abx and f/up 1 week.

Other Meds:

Lab Data: ongoing doctor visits planned, like detox, follow up with specialist..etc. ``` 2/17 and 2/22/2010 Urgent care visit 1/31/2010, Dx Cellulitis lt axillary area Labs/dx studies: None noted

History: unknown ``` 2/17 and 2/22/2010 Urgent care visit 1/31/2010, Dx Cellulitis lt axillary area PMH: None Allergies: Amoxicillin, Ampicillin and Codeine

Prex Illness: unknown guessing on first, second and third dose vaccine given, feel free to look at her records. ``` 2/17 and 2/22/2010 Urgent

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379690-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	05-Feb-2010	05-Feb-2010	0	08-Feb-2010	09-Feb-2010	FL		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	SANOFI PASTEUR	U3056AA	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049CA	3	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Staring, Tremor

Symptom Text: wide eye stare .... passed out and began shaking consistant with a seizure

Other Meds: singular flonase

Lab Data: have not done all the tests yet as we were told he needed to have another episode before he would be seen

History: seasonal allergies

Prex Illness: no none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379771-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Jan-2010	Unknown		09-Feb-2010	09-Feb-2010	CT		25-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Paraesthesia, Vomiting

Symptom Text: Vomiting, paresthesia of hands & feet dizziness pallor. Seen in ER on 01/27/10 @ 10:30 pm, treated and released.

Other Meds:

Lab Data: None

History: Penicillin; KEFLEX

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379791-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Feb-2010	09-Feb-2010	0	09-Feb-2010	09-Feb-2010	GA		09-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1161Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Dizziness, Flushing, Nausea, Vomiting

Symptom Text: Feeling dizzy, nausea, vomiting, flushing BP 100/60 pulse 114 Temp 97.9 resp. 18 monitored and sent home.

Other Meds: None

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379822-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Feb-2010	05-Feb-2010	2	09-Feb-2010	09-Feb-2010	MO		09-Feb-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1203Y	1	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0312	0	Right arm	Unknown	
HEPA	MERCK & CO. INC.	1604	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pain in extremity, Skin warm

Symptom Text: School nurse phoned mother and stated child's L arm was red, swollen, sore and hot to touch. Mother then phoned CDC.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379850-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		09-Feb-2010	10-Feb-2010	FR	WAES1001ISR00011	10-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervix carcinoma

Symptom Text: Information has been received from an ophthalmologist concerning a female (the physician's acquaintance) who was vaccinated with GARDASIL. Subsequently the patient experienced cervical cancer. The reporter felt that cervix cancer was related to therapy with GARDASIL. Upon internal review, cervical cancer was considered to be an other important medical event. This report is one of two reports related by the same source. Additional information has been requested.

Other Meds: unknown

Lab Data: Unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379851-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		09-Feb-2010	10-Feb-2010	FR	WAES1001ISR00012	10-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervix carcinoma

Symptom Text: Information has been received from an ophthalmologist concerning a female (the physician's acquaintance) who was vaccinated with GARDASIL. Subsequently the patient experienced cervical cancer. The reporter felt that cervix cancer was related to therapy with GARDASIL. Upon internal review, cervical cancer was considered to be an other important medical event. This report is one of two reports related by the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **379853-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Feb-2007	01-Oct-2007	215	09-Feb-2010	10-Feb-2010	FL	WAES1001USA03372	08-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2562AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0012U	1	Unknown	Unknown	
	HEPA	MERCK & CO. INC.	1213F		Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Benign intracranial hypertension, Bronchitis, CSF pressure increased, Decreased activity, Diplopia, Headache, Intracranial pressure increased, Lumbar puncture, Muscle twitching, Nausea, Pain, Paraesthesia, Rash, Urticaria, Vision blurred, Visual impairment, Vomiting

Symptom Text: Information has been received from a health professional concerning her daughter an 18 year old female who in October 2007, was vaccinated with the first dose of GARDASIL (lot number not reported). There were no pertinent medical history and drug reactions/allergies. Concomitant therapy included RECOMBIVAX HB (unspecified). The healthcare worker reported that her daughter developed "stabbing head pain associated with a twitch" in approximately October 2007 about 2 weeks after she received her first dose of GARDASIL. The patient had been diagnosed with pseudotumor cerebri which limited her physical activity and she was hospitalized. The patient's pseudotumor cerebri persisted. The patient underwent lumbar puncture to relieve fluid pressure. Multiple unspecified blood tests and diagnostic studies were performed with results not report. Pseudotumor cerebri was considered to be disabling, immediately life-threatening and an other important medical event by the healthcare worker. Follow up information was received from a healthcare professional who reported the patient was vaccinated with the first dose of GARDASIL on 28-FEB-2007, the second dose of GARDASIL on 15-OCT-2007, and the third dose of GARDASIL on 01-JUL-2008 (lot numbers not reported). Concomitant vaccine included MENACTRA received on 28-FEB-2007 and VAQTA (unspecified) received on 28-FEB-2007 and 15-OCT-2007 (lot number not reported). At the 28-FEB-2007 office visit, the patient had bronchitis. At the 15-OCT-2007 office visit, there was no mention of any adverse event. On 23-OCT-2007, the patient was seen for hives and ZYRTEC was given. On 30-OCT-2007, the patient complained of pins and needles all over, rash was gone. On 28-NOV-2007, the patient complained of blurred vision, and a neuro consult was directed. In November and December 2007, the patient was admitted to the hospital (no other details available). In November 2008, the patient was admitted for nausea, vomiting and headache (no other details). On 05-JUN-2009, the patient was last seen in their o

Other Meds:

Lab Data: Unknown ``02/15/10 LABS and DIAGNOSTICS: Ct-normal, MRI-abnormal (abnormal clivus), LP-abnormal (elevated opening pressure), CSF cult-neg., Bone scan-normal (no abnormality or bony lesion of the clivus), Three-view cervical spine x-ray-n

History: None ``` 02/15/10 PMH: allergy to shellfish, intermittent asthma, Tics

Prex Illness: Bronchitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379855-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Feb-2010	07-Feb-2010	1	09-Feb-2010	09-Feb-2010	CA		10-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3247AA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	V3044AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	2049Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Chills, Injection site cellulitis

Symptom Text: Dev temp to 105 degrees with chills, cellulitis left deltoid area after vac.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379856-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Oct-2009	04-Oct-2009	3	09-Feb-2010	10-Feb-2010	NY	WAES1001USA03373	10-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Angioedema, Dyspnoea, Eye swelling, Laboratory test normal, Petechiae, Urticaria

Symptom Text: Information has been received from a physician concerning a 20-21 year old female with allergic to cats and no known drug allergies who on 01-OCT-2009 was vaccinated with the third dose of GARDASIL (lot number not reported). There was no concomitant medication. On 04-OCT-2009 3 days after the third dose, the patient developed hives (petechial rash on lower extremities), angioedema, right eye swelling, shortness of breath and abdominal pain and was hospitalized. The patient was hospitalized several times, all testing came back normal. The patient was treated with steroids. The patient's hives (petechial rash on lower extremities) and angioedema and right eye swelling and shortness of breath and abdominal pain persisted. No further information is available.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Allergic to cats

Prex Vax Illns:

Vaers Id: 379857-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Jun-2009	07-Jul-2009	7	09-Feb-2010	10-Feb-2010	IN	WAES1001USA03374	08-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Abdominal tenderness, Activities of daily living impaired, Blindness, Breath sounds abnormal, Bronchitis, Condition aggravated, Cough, Deafness, Dizziness, Fatigue, Gastrooesophageal reflux disease, Headache, Heart rate decreased, Intestinal functional disorder, Loss of consciousness, Lymphadenopathy, Nasal congestion, Oropharyngeal pain, Presyncope, Renal cyst, Similar reaction on previous exposure to drug, Sinus operation, Syncope, Upper respiratory tract infection, Weight decreased

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female patient with sulfonamide and azithromycin allergy who on 30-JUN-2009 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot# 659655/0940X). On 01-SEP-2009 the patient was vaccinated intramuscularly with the second 0.5ml dose of GARDASIL (lot# 663452/0671Y). Concomitant therapy included SPRINTEC. On approximately 07-JUL-2009 ("a week after administration of her first dose of GARADSIL"), the patient experienced fainting spells, stomach pains, weight loss of 16 pounds, swollen glands in the neck and fatigue. It was reported that the patient experienced the same symptoms but more intense after her second dose of GARDASIL administered on 01-SEP-2009. When she experienced a fainting spell, she was exhausted for the rest of the day. The patient still continued to have episodes of blacking out and stomach pain once or twice a week. The patient had been examined and had a complete work up from a neurologist, gastrologist and cardiologist. All tests were negative. At the time of this report, the patient was recovering. Follow up information has been received from the medical assistant who confirmed the dates and lot #s for the two doses of GARDASIL and reported that there were no concomitant vaccines were administered. She clarified that the events, experienced a week after the first dose, persisted then worsened after administration of the second dose. The events were considered as disabling since the patient could not attend school. It was unknown if the patient was hospitalized. The patient had not seen in their office since 01-SEP-2009. Fainting spells, stomach pains, weight loss of 16 pounds, swollen glands in the neck, fatigue and episodes of blacking out were considered to be disabling. Additional information has been requested. ``` records received 02/10/10 & 02/11/10. Clinic rec and cardiology, neurology and ENT consults for DOS 06/30/09-12/14/09. Patient presented with c/o lightheadedness, visual loss, he

Other Meds: SPRINTEC

Lab Data: Physical examination, negative--a complete work up from a gastrologist and cardiologist; neurological, negative ``` 02/11/10 LABS and DIAGNOSTICS: Audiometric studies-normal, MRI brain-neg., echocardiogram-normal. Monitor test (day) - norm

History: ``` PMH: Allergy to Sulfa and Zithromax, menorrhagia. ``` PMH: Episodes of presyncope for several years.

Prex Illness: Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **379858-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Jan-2010	29-Jan-2010	0	09-Feb-2010	10-Feb-2010	FR	WAES1002COL00001	10-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a physician concerning a 17 year old female who in November 2009 (day unknown), was vaccinated with the first dose of GARDASIL, and on 29-JAN-2010 was vaccinated with the second dose of GARDASIL. On 29-JAN-2010 after the application of the vaccine, the patient experienced syncope for 1 minute and convulsion for 40 seconds. Subsequently, the patient recovered from syncope and convulsion without sequels. The patient did not consult to the emergency room and did not receive any treatment. The reporter felt that syncope and convulsion were related to therapy with GARDASIL. Upon internal review, the patient's convulsion was considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **379859-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Mar-2009	Unknown		09-Feb-2010	10-Feb-2010	FR	WAES1002USA00090	10-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diabetes mellitus, Guillain-Barre syndrome, Miller Fisher syndrome, Myopathy

Symptom Text: Information has been received from a health care professional. This case is poorly documented. It was reported by a general practitioner that an adolescent female patient was vaccinated with a dose of GARDASIL (lot number and dose in series not reported) IM into the upper arm in Spring 2009. Unspecified time post vaccination, the patient developed a MILLER FISHER syndrome, suspicion of GUILLAIN-BARRE syndrome, myopathy and diabetes mellitus. Non-specific autoimmune processes were assumed. At the time of reporting, the patient was treated with gabapentin. The further course and outcome were not reported. The events of autoimmune disorder, GUILLAIN-BARRE syndrome, MILLER FISHER syndrome, myopathy and diabetes mellitus were considered Other Medically Important Conditions. Other business partner numbers include: E2010-00607. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **379860-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		09-Feb-2010	10-Feb-2010	FR	WAES1002USA00524	10-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a pediatrician concerning a 17 year old female patient with no history reported who was vaccinated with a dose of GARDASIL (lot#, injection route and site not reported) on an unspecified date. Subsequently the patient developed multiple sclerosis. The patient's outcome was unspecified. The multiple sclerosis was determined to be serious as an other important medical event. Other business partner number include E2010-00726. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 379861-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	F	30-Jan-2009	01-Oct-2009	244	09-Feb-2010	10-Feb-2010	--	WAES0902USA03113B1	01-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Congenital anomaly, Drug exposure during pregnancy, Hepatoblastoma, Hepatomegaly, Mass

Symptom Text: information has been received from a registered nurse from a completed questionnaire from a pregnancy registry concerning a female baby, whose mother had a history of 0 pregnancies and 0 live births and a concurrent condition of venous angioma and a history of cervical dysplasia. On 30-JAN-2009, the mother was vaccinated with the third dose of GARDASIL (lot no. 660618/0572X) 0.5 ml, IM. First dose was given 30-JAN-2007 and second dose on 30-MAR-2007 (Lot # 656049/0187U). Concomitant therapy included prenatal vitamins (unspecified). On 06-FEB-2009 the mother found out she was pregnant. On 06-OCT-2009, the patient born weighing 7 lbs 12 oz, length 20 cm and Apgar score 9/9. At pediatrician visit at 8 weeks, a "patoblastoma" was discovered. Additional information was received from a registered nurse and a consumer. The consumer clarified that her daughter had a "hepatoblastoma, a tumor on her liver." She said it was during a well-baby check that the pediatrician noted an enlarged liver. The baby was referred to oncologist. The registered nurse reported that it was the pediatrician who ordered the ultrasound which was performed on 11-DEC-2009. The study showed a 10 X 7.2 cm mass in the right lobe of the liver. The baby was then admitted to the hospital. A Computed Tomography scan done on approximately 11-DEC-2009 showed a large mass. A Magnetic Resonance Imaging was also done (results not provided). On 15-DEC-2009, a biopsy and the elevated (60,527) alpha fetoprotein (AFP) test confirmed the hepatoblastoma. Chemotherapy was started on 18-DEC-2009. At present, the baby was doing well. The latest AFP was down to 500. Chemo continued and eventually surgery would be required. The registered nurse could not link any causality to the hepatoblastoma. The mother's experience has been captured in WAES 0902USA03113. Hepatoblastoma was considered to be a congenital anomaly. Additional information has been requested.

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 12/11/09, showed a 10 X 7.2 cm mass in the right lobe of the liver; Computed axial, 12/11?/09, showed a large mass; Magnetic resonance, 12/11?/09, results not provided; Biopsy, 12/15/09, confirmed the hepatoblastoma; Serum alpha

History: Cervical dysplasia

Prex Illness: Angioma

Prex Vax Illns:

Vaers Id: **379874-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jul-2009	29-Aug-2009	44	09-Feb-2010	10-Feb-2010	FR	WAES1001USA03762	10-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Completed suicide, Death, Poisoning

Symptom Text: Information has been received from a physician concerning a 14 year old school going girl (ID#: -3/09) who received the first dose of GARDASIL in left deltoid, on 16-JUL-2009. Concomitant therapy included indigo. During the process of community mobilization for second dose, the female health worker was informed that the patient committed suicide on 29-AUG-2009 by consuming insecticide. The postmortem was performed on 30-AUG-2009. This event occurred after 45 days of receiving first dose of GARDASIL. The female health worker informed the medical officer in charge, which was then communicated to Immunization Officer. The medical officer in charge investigated the death and completed first information report as per guidelines and determined the death was not related to the vaccine and so no further investigations were done. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379875-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	01-Dec-2009		09-Feb-2010	10-Feb-2010	--	WAES1002USA00346	10-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1694U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Leukaemia

Symptom Text: Information has been received from the agency via a Case Line Listing via CSL, as part of a business agreement, concerning a 17 year old female who on 04-SEP-2009 was vaccinated IM with a second 0.5ml dose of GARDASIL (lot# 1694U, batch# NJ21420). In December 2009, less than 1 year after vaccination, the patient experienced leukaemia (severe) and was hospitalized. The patient's leukaemia persisted. The reporter felt that leukaemia was unlikely related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379876-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Jul-2009	21-Jan-2010	186	09-Feb-2010	10-Feb-2010	FR	WAES1002USA00379	10-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: DIED, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Completed suicide, General physical health deterioration, Poisoning deliberate

Symptom Text: Information has been received from a physician concerning a 13 year old school going girl (ID#: -104/09) of class eight. On 19-JUL-2009, patient received first dose of GARDASIL left deltoid (lot#876, manufacturing date June 2008). Patient successfully completed her second dose on 13-OCT-2009. She was due with her third dose. On 21-JAN-2010, she was reported to have consumed poison around 9:00 am. She was taken to the area hospital and provided preliminary emergency treatment. She was provided DECADRON injection 2 cc, injection dopamine 1 amp. in 5% dextrose 10-12 drops/min, injection deriphylline I.V 8 hourly, injection diazepam 1 amp. IV, Ryle's tube aspiration and stomach wash. It was advised to record her temperature, pulse, respiration, and blood pressure half hourly and had oxygen inhalation. High risk consent was taken. As her condition started to deteriorate she was shifted to another hospital by '108 emergency service' for further evaluation and management. On the way to the hospital, it was reported to have expired around 2:00 pm on 21-JAN-2010. The hospital noted the case was "brought dead". The postmortem was performed on 22-JAN-2010 and the results are awaited. The medical officer in charge investigated the death and completed first information report and determined the death could be suicide (due to poison intake) and not related to the vaccine. This report was part of a post-marketing surveillance program.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **379965-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Aug-2009	09-Oct-2009	62	11-Feb-2010	11-Feb-2010	TX		15-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
DTAP	SANOFI PASTEUR	UF485BA	2	Unknown	Unknown	
HPV4	MERCK & CO. INC.	0570X	1	Unknown	Unknown	
VARCEL	MERCK & CO. INC.	02254	1	Unknown	Unknown	
MNQ	SANOFI PASTEUR	U2873AA	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Chest pain, Conversion disorder, Convulsion, Dyskinesia, Dyspnoea, Hyperventilation, Migraine, Muscle spasms, Muscle twitching, Pallor, Paraesthesia, Posturing, Staring, Syncope, Unresponsive to stimuli, Visual impairment

Symptom Text: difficulty breathing, seizure, muscle spasms...first trip to ER. ```2/15, 3/1 & 3/2/10 Outpatient records and neurology consult received for dates of service 1/18/09 to 2/22/10. Dx: Seizures. Common migraine. Pt. awoke having trouble breathing and hyperventilated, had tingling and cramping of hands. Grabbed chest then cramped up and had body contortions and then staring. Pale during episode. C/o chest pain with seizure like episode with posturing, jerking and staring. Episodes last hours. Some regression of behavior. Had a LP with spinal HA and subsequent blood patch. Diagnosed with conversion disorder. Twitching of extremities and trouble with vision. Neorological exam positive for fainting, headaches, involuntary movements, seizure and staring, unresponsive spells. ```3/10/10 DC summary received for dates 10/19/09 to 10/21/09. DX: conversion disorder, pseudoseizure. CC: feeling anxious, chest pain, difficulty breathing progressing to irregular movement of bilat extremities. Repeating a single word several times, confused somewhat unresponsive. Assessment: WNL, all testing WNL, psychiatric f/u advised.

Other Meds: none

Lab Data: EEG, MRI,CAT scan, multiple blood work-ups, neurologist tx, EKG. ```2/15, 3/1 & 3/2/10 Outpatient records and neurology consult received for dates of service 1/18/09 to 2/22/10. Labs and diagnostics: EEG-WNL. LP-Normal. ```3/10/10 Dia

History: none. ```2/15, 3/1 & 3/2/10 Outpatient records and neurology consult received for dates of service 1/18/09 to 2/22/10. PMH: None.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **379970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Dec-2009	05-Dec-2009	4	10-Feb-2010	11-Feb-2010	FR	WAES1001USA03713	11-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ29430	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Agitation, Aphasia, Asthenia, Confusional state, Dysstasia, Headache, Hemiparesis, Laboratory test abnormal, Migraine, Paraesthesia, Psychomotor hyperactivity, Speech disorder, Vision blurred

Symptom Text: Case reported by Health Authority (case n. 110513) (local case n. IT038/10). Initial report received on 26-JAN-2010. An 11 year old female patient with no previous medical history who on 01-DEC-2009 was vaccinated with the first dose of GARDASIL (lot# NJ29430, batch# NK18100) IM. On 05-DEC-2009 the patient presented with a strong migraine associated with right hemiparesis, speech difficulty, confusional state. She was taken to the ER where she was treated with TACHIPIRINA without benefit and NOVALGINA. She was evaluated by a neurologist that diagnosed "confusional migraine". The case was reported as not serious by both the HA and the reporter and upgraded to serious by Company based on internal rules. The outcome is recovered on 06-DEC-2009. The case is closed. To note, Health Authorities coded only confusion, hemiparesis and migraine. Follow-up information has been received on 05-FEB-2010: the report by the patient's physician was received through HA. The patient's maternal grandmother has a positive history for migraine; her paternal grandmother has a positive history for bitemporal headache. At 6 months of age the patient presented with scarce usage of the upper right limb for which she was evaluated neurologically for which she underwent physical therapy. She regained complete function within one year. From 6-8 year of age she suffered from headaches monthly. Positive for allergy to amoxicillin (+) clavulanate potassium and azithromycin (cause face angioedema). On 01-DEC-2009 the patient was vaccinated the first dose of GARDASIL (lot# NJ29430, batch# NK18100) with no adverse effect. She was engaged in swimming at an agonistic level. On 05-DEC-2009, following 3 hours of swimming practice, the patient presented with nuchal headache followed one hour later by dysphasia, paresthesia of the right hemisoma and blurring of the right eye. She was taken to the ER where she still presented with psychomotor agitation, dysphasia, inability to keep the standing posture because of hyposthenia right hemisoma, testing positi

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, 11Jan10, negative; neurological examination, 25Jan10, negative

History: Upper extremity dysfunction

Prex Illness: Headache; Penicillin allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **379988-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	05-Feb-2010	07-Feb-2010	2	10-Feb-2010	11-Feb-2010	MO		11-Feb-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1378Y	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365CA	1	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1202Y	1	Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B093DA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U30B0AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Induration, Injection site erythema, Injection site swelling

Symptom Text: (R) tricep area with 6.5 x 4 cm erythema and mild swelling - (L) tricep area with 13 x 9 outer erythema/swelling and central 4.5 x 3cm red/indurated area, tx with KEFLEX.

Other Meds: MIRALAX; Metformin

Lab Data:

History: Insulin resistant

Prex Illness: No

Prex Vax Illns:

Vaers Id: 380047-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Feb-2010	02-Feb-2010	0	11-Feb-2010	12-Feb-2010	MO		05-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Conversion disorder, Dizziness, Photophobia, Tonic clonic movements, Vision blurred

Symptom Text: Grand mal seizure activity. By the time parent reported the situation to the health dept on 2/11/2010, the parent reported that the child had 88 seizures. ``` 2/12 and 2/16/2010 MR, DC summary for 2/3-2/5/2010, Dx Pseudoseizure patient with sx of seizure activity with tonic/clonic movements, photophobia, blurred vision, dizziness, tx'd with IV fospheenytoin, Ativan, Klonopin

Other Meds: None.

Lab Data: ``` 2/12 and 2/16/2010 MR, DC summary for 2/3-2/5/2010, Dx Pseudoseizure Labs: CBC, BMP, HCG, UA and urine drug screen all wnl/negative Dx studies: CT head, MRI and MRA Brain and EEG wnl

History: None. ``` 2/12 and 2/16/2010 MR, DC summary for 2/3-2/5/2010, Dx Pseudoseizure PMH: None Allergies: NKDA

Prex Illness: None. ``` 2/12 and 2/16/2010 MR, DC summary for 2/3-2/5/2010, Dx Pseudoseizure

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380051-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	09-Feb-2010	10-Feb-2010	1	11-Feb-2010	12-Feb-2010	ID		12-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1333Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Swelling face

Symptom Text: Swelling, erythema, itching of face

Other Meds: Oral contraceptives (patient didn't know name of OCP)

Lab Data: N/A

History: N/A

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380081-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Jul-2009	08-Aug-2009	22	12-Feb-2010	12-Feb-2010	FR	WAES1001USA03765	12-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: DIED, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Coma, Death, Dyspnoea, Pyrexia

Symptom Text: Information has been received from a physician concerning a 13 year old school girl studying in class nine of health center. On 17-JUL-2009, patient received first dose of GARDASIL left deltoid. Concomitant medications included chloroquine, RANTAC, paracetamol, "IV fluids RL" and aminophyline drip. During the process of community mobilization for second dose of GARDASIL the multipurpose health worker was informed that the patient developed fever on 01-AUG-2009 and was treated by local registered medical practitioner (RMP). The patient did not recover and was admitted to the hospital on 08-AUG-2009. On the same day, GENTAMYCIN was given. She developed dyspnoea and went into coma and so was referred and was shifted to another hospital where she expired on 08-AUG-2009 at around 9:00 pm. The cause of death was determined as "death due to viral fever". The information was provided from patient's maternal grandparents as she was staying with them. This event occurred after 23 days of receiving first dose of GARDASIL. The female health worker informed the medical officer in charge and he investigated the death and completed the first information report as per AEFI guidelines. The case sheet mentions as "pyrexia of unknown origin". This information was then communicated to district immunization officer, who determined that the death was not related to the vaccine and so a decision was taken to close the investigation.

Other Meds: RANTAC; acetaminophen, aminophylline; chloroquine

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **380160-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Feb-2010	05-Feb-2010	1	12-Feb-2010	15-Feb-2010	NC		15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia

Symptom Text: PT WAS AT GYM CLASS-SHE DID ONE PUSH UP AND FELT WEAK AND WENT TO ED FOR EVALUATION

Other Meds: TAKES BIRTH CONTROL PILLS

Lab Data: U/A NEG, CBC-NORMAL, EKG-NORMAL

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **380188-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
31.0	F	09-Feb-2010	09-Feb-2010	0	12-Feb-2010	15-Feb-2010	FR	WAES1002KOR00021	01-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Syncope, Vomiting

Symptom Text: Information has been received via a business partner company from a 31 year old female who on 09-FEB-2010 was vaccinated with GARDASIL (intentional use for unlabelled age). On 09-FEB-2010 the patient experienced passing out and one vomiting while unconscious. It happened while she was massaging the injection site with an alcohol swab at the hospital right after the vaccination. The patient received unspecified treatment, and recovered in an hour without any problems. Upon internal review in the business partner company, syncope was considered to be an other important medical event. The causality with GARDASIL was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **380189-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Oct-2009	Unknown		12-Feb-2010	15-Feb-2010	--	WAES1002USA00451	15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a consumer concerning his daughter who in October 2009, was vaccinated with the first dose of GARDASIL (dose not reported). On unknown dates, the patient received the 2nd and 3rd dose of GARDASIL (doses not reported) (lot #s 661841/0653X, 661846/1312X and 663452/0671Y; unspecified the schedule in which each lot # was administered). On an unknown date, the patient experienced a seizure after receiving GARDASIL. The patient's outcome at the time of the report was unknown. It was unknown if the patient sought medical attention. In follow-up the patient's father did not provide any further details or contact information. This is one of two reports from the same source. A lot check has been initiated. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **380190-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		12-Feb-2010	15-Feb-2010	--	WAES1002USA00661	15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a consumer reporting that he knows of several cases of seizures after receiving GARDASIL vaccine. Upon internal review, seizures was considered to be an other important medical event. This is a hearsay report in the absence of an identifiable patient. Attempts to verify the existence of a patient have been unsuccessful. This is one of two reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **380191-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	13-Jan-2010	13-Jan-2010	0	12-Feb-2010	15-Feb-2010	--	WAES1002USA00990	15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Deafness, Headache

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female patient with no known allergies or pertinent medical history, who on 13-JAN-2010 was vaccinated with the first dose of GARDASIL (lot number and route not reported). Concomitant therapy included hormonal contraceptives (unspecified). On approximately 13-JAN-2010 "within 24 hours after vaccination", the patient experienced severe headache and hearing loss for 5 hours. On approximately 13-JAN-2010, the patient went to the emergency room. On 14-JAN-2010 the patient recovered from the severe headache and the hearing loss. No tests or studies were performed. Upon internal review, the hearing loss was considered to be an other important medical event. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: **380192-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Oct-2009	16-Oct-2009	0	12-Feb-2010	15-Feb-2010	FR	WAES0912USA03177	15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1648U	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Chest pain, Dysaesthesia, Guillain-Barre syndrome, Hyperaesthesia, Hypersensitivity, Incorrect route of drug administration, Myalgia, Nervous system disorder, Pain, Paraesthesia, Vertigo

Symptom Text: Information has been received from a physician concerning an adolescent female (age unspecified) who in October 2009, was vaccinated with the first dose of GARDASIL (batch number not reported). Three days after vaccination, the patient presented with a partial "little reaction evoking a Guillain Barre Syndrome", characterized by thoracic pain, hyperesthesia of the lower limbs and metameric hypersensitivity. The reaction regressed within 10 days. The pain evoked a zona, but this diagnosis was ruled out. At the time of reporting, the patient had recovered. Upon internal review the event was considered medically significant. Follow-up information received through PV form, neurological reports and laboratory results on 29-JAN-2010: This is a case of misuse. The patient was 14 years old. She received her first dose of GARDASIL (batch number NH43700, lot number 1648U) via subcutaneous route-instead of intramuscular as recommended-in the left arm or the left shoulder on 16-OCT-2009. 48 hours after vaccination, she experienced myalgias during 8 days. Three days after vaccination, she developed neurological disorder during 15 days. She presented with a significant left dorsal dysesthesia with spread to the left lower limb. This was also three days after vaccination. The clinical examination showed a D4-D10 left dysesthesia, as well as a dysesthesia of the anterior and internal face of the left thigh. There was no motor deficit, osteotendinous reflexes were sharp and symmetric. Cutaneous plantar reflexes were present. The neurologist saw her again on 02-NOV-2009 to perform an electromyography. The patient reported then that her dorsal paresthesias and paresthesia of the left lower limb and almost completely regressed. Biological work-up (hematology and blood chemical work-up) was normal and concluded to a normal electrophoretic profile. The electromyography was normal and did not show any sign of neurogenic pain in the lower limbs. The reporter added that the patient also experienced pain when walking, severe asthenia, pai

Other Meds: Unknown

Lab Data: Electromyography, normal, did not show any sign of neurogenic pain in the lower limbs; Serum C-reactive protein, <7; Serum LDH, normal; Serum alanine aminotransferase, normal; Serum aspartate aminotransferase, normal; Serum blood urea,

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **380223-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-Feb-2010	15-Feb-2010	NY	WAES1002USA01143	15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia, Nervous system disorder

Symptom Text: Information has been received from a physician, who reported that she heard from patient, that a local physician had a teenaged patient who experienced dehabilitating numbness in the arm and neurological disorders (unspecified) after administration of GARDASIL vaccine (dose in series, route and lot number not reported). In follow-up, the physician stated that the patient events were not verified by her. The physician considered severe numbness in the arms as disabling. The patient outcome at the time of the report was unknown. It was unknown if the patient sought medical attention. The healthcare professional contacted during telephone call, could not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number, lot number, date of event, recovery status, hospital name, healthcare provider name and contact information. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380224-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-Feb-2010	15-Feb-2010	NY	WAES1002USA00766	15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia, Nervous system disorder

Symptom Text: Information has been received from a physician, who reported that she heard from patient, that a local physician had a teenaged patient who experienced dehabilitating numbness in the arm and neurological disorders (unspecified) after administration of GARDASIL (dose in series, route and lot number not reported). In follow-up, the physician stated that the patient events were not verified by her. The physician considered severe numbness in the arm as disabling. The patient outcome at the time of the report was unknown. It was unknown if the patient sought medical attention. The healthcare professional contacted during telephone call, could not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number, lot number, date of event, recovery status, hospital name, healthcare provider name and contact information. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **380225-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	27-Jan-2009	12-Mar-2009	44	12-Feb-2010	15-Feb-2010	FR	WAES1002USA00737	15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Antineutrophil cytoplasmic antibody positive, Diffuse vasculitis, Renal vasculitis

Symptom Text: Information was obtained on request by the company from the agency via a public case details form concerning a 23 year old female patient who on 27-JAN-2009 was vaccinated intramuscularly with a dose of GARDASIL (Lot not reported). On 12-MAR-2009 the patient experienced multisystem vasculitis with renal involvement, antineutrophil cytoplasmic antibody positive and diffuse vasculitis. Biopsy showed severe vasculitis associated with p-ANCA. The patient correlated the onset of her illness with GARDASIL vaccination 6 weeks prior. Treating clinician (a nephrologist) did not believe there was a clear causal relationship but there was a temporal association. Prior to vaccination patient suffered from arthralgia, weight loss and fatigue. The patient was placed on therapy with cyclophosphamide, prednisolone, rituximab, azathioprine. At the time of report the patient's status was not yet recovered. The agency considered that all the symptoms were related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: biopsy, showed severe vasculitis associated with p-ANCA; serum ANCA, positive

History: Arthralgia; Weight decreased; Fatigue

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380226-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	15-Jun-2009		12-Feb-2010	15-Feb-2010	FR	WAES1002USA00707	15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Grand mal convulsion, Similar reaction on previous exposure to drug, Syncope

Symptom Text: Information was obtained on request by the company from the agency via a public case details form concerning a 12 year old female patient who on an unspecified date was vaccinated with the first and second doses of GARDASIL. On 15-JUN-2009 the patient experienced syncope and grand mal convulsion. After the first dose of GARDASIL daughter became faint at school. After the second dose of GARDASIL daughter also became faint at school. Five weeks after second dose daughter experienced her first grand mal tonic-clonic seizure, 10 days following another seizure occurred resulting in being taken to hospital (specialist suspected daughter had had other seizures in her sleep). Lab data: albumin test with the result unknown. At the time of report the patient's status was not recovered. The agency considered that all the symptoms were related to therapy with GARDASIL and to be incapacity/disability. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: serum albumin

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **380227-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-Feb-2010	15-Feb-2010	NY	WAES1002USA00013	15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a physician concerning a female patient (age not reported), who was vaccinated with a dose of GARDASIL (dose and lot not reported). Physician stated that a patient experienced severe numbness in her arm for 2 weeks after administration of GARDASIL. This occurred 1 to 2 years ago. In follow-up, the physician stated that she had no available information concerning the patient, since she was vaccinated and treated at another office. The physician considered that severe numbness in her arm was disabling. The patient's outcome at the time of the report was unknown. Patient sought medical attention via office visit. The healthcare professional contacted during telephone call, could not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number, lot number, date of event, recovery status, hospital name, healthcare provider name and contact information. This is one of two reports from the same source. No further information is available.

Other Meds: unknown

Lab Data:

History: unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380228-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Aug-2008	15-Dec-2008	115	12-Feb-2010	15-Feb-2010	CA	WAES1001USA03685	15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL concerning a 16 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who on 22-AUG-2008 was vaccinated with the first dose of GARDASIL. There were no concomitant medications reported. It was reported that the patient received the first dose of GARDASIL and got pregnant. On 21-OCT-2009, the patient got the second dose of GARDASIL Lot #0702) and the third dose on 01-DEC-2009 after having the baby. The patient had a "normal prenatal care". The patient sought medical attention with an office visit. All telephone attempts to obtain follow up information have been unsuccessful. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 12/25/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380303-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
30.0	F	10-Feb-2010	10-Feb-2010	0	13-Feb-2010	15-Feb-2010	TX		15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Ear pain, Fatigue, Headache, Muscular weakness, Musculoskeletal stiffness, Pain, Pain in extremity, Toothache

Symptom Text: Weakness and pain in joints of injection arm. Later that day, stiffness and soreness and neck and shoulders. The next day, stiffness and soreness in muscles and joints, increasing throughout the day. The third day, stiffness continues, headache and toothache that does not improve with ibuprofen. Forth day, horrible headache with toothache, ear ache, muscle stiffness, body soreness, fatigue. Ibuprofen does not help.

Other Meds: Ibuprofen Sudafed

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380320-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		15-Feb-2010	15-Feb-2010	NY		15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Persistent stabbing pain at injection x 6 wk.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380330-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	15-Jan-2010	17-Jan-2010	2	15-Feb-2010	15-Feb-2010	OR		15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP032AA	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3366AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eczema, Injection site reaction

Symptom Text: Eczema like reaction around injection site.

Other Meds:

Lab Data: No

History: NKDA

Prex Illness: Abdominal pain

Prex Vax Illns:

Vaers Id: **380346-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Jan-2010	27-Jan-2010	1	15-Feb-2010	15-Feb-2010	ID		15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Chills, Dizziness, Nausea

Symptom Text: Got GARDASIL #3 vaccine 1-26-10. That night woke up at 0100 with chills/dizziness. Temp 101 @ 0430 with nausea.

Other Meds: None

Lab Data: None

History: None known

Prex Illness: None

Prex Vax Illns:

Vaers Id: **380385-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Jan-2010	26-Jan-2010	0	15-Feb-2010	15-Feb-2010	TX		14-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	1013273P	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1353Y	0	Left arm	Intramuscular	
FLU	SANOFI PASTEUR	UT3175AA	0	Right arm	Intramuscular	
HEPA	MERCK & CO. INC.	16004X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea, Vaginal discharge, Vomiting

Symptom Text: Patient pregnant. ``` records received 02/15/10 & 02/19/10. Immunization rec and Initial new patient office visit rec. and lab. tests for 02/09/10. Dx: Pregnancy exam positive, Nausea & vomiting, Vaginal discharge. Patient (G1/P0) presents for initial visit. LMP was 12/26/09. Gestation 7W 6D. Examination noted uterus 10 wk. size and vagina had moderate amount white discharge. Plan: to schedule sonogram before next visit. RTC in 4 wks.

Other Meds:

Lab Data: Urine HCG + ``` 02/19/10 LABS and DIAGNOSTICS: Urine HCG-positive, Pap report-abnormal (Atypical squamous cells of undetermined significance), WBC-13.0 (WNL), Platelet ct-363 (WNL), RBC-4.38 (WNL), Absolute neutrophils-9919 (H), Absolute l

History: ```02/19/10 PMH: Allergy to Naprosyn and Ibuprofen.

Prex Illness: Pregnant

Prex Vax Illns:

Vaers Id: 380395-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Apr-2009	22-Apr-2009	0	15-Feb-2010	16-Feb-2010	FR	WAES0911USA04796	16-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1883U	2	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abscess drainage, Breast abscess, Incorrect route of drug administration, Induration, Lymphadenopathy, Nodule, Similar reaction on previous exposure to drug, Staphylococcal infection

Symptom Text: Case received from a health care professional on 20-NOV-2009. A 14 year-old female patient received a third dose of GARDASIL (batch number not reported) on an unspecified date. Following vaccination, she presented with an abscess on her breast. She had already experienced the same reaction after receiving the second dose of GARDASIL (batch number not reported). The abscess had disappeared later on an unspecified date before reappearing after the third dose. At the time of reporting, the outcome was not reported. Follow-up information received through PV form and hospital report on 17-DEC-2009: This is a case of misuse. The patient had received the first dose of GARDASIL (batch number NH 50490, lot# 1883U) on 22-APR-2009 and the third dose GARDASIL (batch number NJ33350, lot#1202U) on 15-OCT-2009, both via subcutaneous route instead of intramuscular as recommended-in the left deltoid. 31 days after receiving the first dose (instead of the second dose as previously reported), the patient had experienced a periareolar abscess on the right breast which had necessitated a surgical drainage. Bacteriological examination had revealed a staphylococcus epidermidis infection. The patient had been treated with OFLOCET 1 dosage form Bid during 8 days and had recovered. 25 days after receiving the third dose, she developed an abscess on the right breast, associated with axillary adenopathy. She was seen by the reporter on the first day when she presented with the abscess. She was treated with AUGMENTIN and recovered on an unspecified date. No further information expected. Additional information received on 21-JAN-2010: The physician reported that no tests had been performed and she could not confirm whether it was the same infection or not. She did not know whether the patient had adenopathies during the first episode of events. At the time of the second abscess, the patient was found with C-reactive protein (CRP) at 8.7. a sedimentation rate of 20 mm then 46 mm. she considered the relation with vaccination as possible. Follow

Other Meds: Unknown

Lab Data: Serum C-reactive protein, ??09, 8.7; Gram stain bacteria test, 24?May09, revealed a staphylococcus epidermidis infection; Erythrocyte sedimentation rate, ??09, 20 mm; Erythrocyte sedimentation rate, ??09, 46 mm

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380396-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-Apr-2008	04-Aug-2009	476	15-Feb-2010	16-Feb-2010	FR	WAES1002USA00705	16-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Injection site erythema, Injection site infection, Injection site pain, Injection site swelling

Symptom Text: Information was obtained on request by the company from the agency via a public case details form concerning a 21 year old female who on 15-APR-2008 was vaccinated intramuscularly with a dose of GARDASIL (LOT# not reported). On 04-AUG-2009 (also reported as onset within 3 to 4 hours post injection), the patient experienced injection site reaction and injection site infection required a visit to the physician and was hospitalized. It was reported that injection site was tender, red and raised. Nil LN increased, WCC 27, Neut 22 and CRP 300. The patient treated with IV flucloxacillin. At the time of reporting, the patient had not recovered yet. The agency considered that all the symptoms were probably related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: WBC count, 27; Neutrophil count, 22; Serum C-reactive protein, 300

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **380397-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Feb-2010	03-Feb-2010	0	15-Feb-2010	16-Feb-2010	NJ	WAES1002USA00789	16-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0670Y	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Gaze palsy, Inappropriate schedule of drug administration, Loss of consciousness, No reaction on previous exposure to drug, Tremor

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female with PENICILLIN allergy, who tends to pass out with needles and whose father had epilepsy (had a brain injury 20-25 years ago de to an accident) who on 03-FEB-2010 was vaccinated intramuscularly with third 0.5mL dose of GARDASIL (lot number 0670Y). There was no concomitant medication. The medical assistant reported that one and a half minutes later, the patient said she was going to pass out and then the patient passed out. The patient's eyes rolled back, she shook which lasted 15 seconds. The mother's words were "she's having a seizure" and she was holding down the patient. The patient was watched at the office for 30 minutes after this occurrence and she was fine. It was noted that the patient received the first and second doses of GARDADIL at another provider's office. The second dose of GARDASIL (dose, route and lot number not reported) was given on year ago (in February 2009). The patient did not report any problems with the first and second doses of GARDASIL. It was noted that the patient's mother was going to have her daughter follow up with a neurologist. No lab studies were performed. The patient sought unspecified medical attention. On 03-FEB-2010 the patient recovered. Follow up information was received from the office receptionist. It was reported that the patient received did not received other vaccinations at the time of the third GARDASIL vaccine on 03-FEB-2010. Upon internal review, she's having a seizure was determined to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Passed out; Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380398-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	02-Feb-2010		15-Feb-2010	16-Feb-2010	--	WAES1002USA00790	16-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female who on an unspecified date was vaccinated with second dose of GARDASIL (dose, route and lot number not reported). The registered nurse stated that after her second dose of GARDASIL, on 02-FEB-2010, she fainted and had seizure like movements. the patient sought unspecified medical attention. Upon internal review, seizure like movements was determined to be an other important medical event. Additional information has been requested.

Other Meds: unknown

Lab Data: Unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **380400-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Feb-2009	Unknown		15-Feb-2010	16-Feb-2010	FR	WAES1002USA01070	16-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Painful respiration, Pericardial drainage, Pericarditis, Pleurisy, Pulmonary embolism, Pyrexia, Upper respiratory tract infection

Symptom Text: Information has been received from a Health Authority (HA ref. 096248) concerning an 18 year old female was vaccinated with the second dose of GARDASIL (batch number and route unknown) on unspecified date in February 2009. HA coded pericarditis (causality unclassifiable) with onset in 2009 (date unspecified). In connection to vaccination (date unknown), the girl experienced periods of fever, painful respiration and increased CRP (=71, Ref. <3). Findings (unspecified) of pericardial and plural liquid were make some weeks later which resulted in hospitalization. The girl remained hospitalized for 10 days on treatment with pericardial drainage, antibiotics (mfr other), NSAIDs (mfr unknown) and prednisolone (mfr other). Investigation including rheumatology and infection consultant could not establish an obvious genesis of pericarditis. A suspicion of mycoplasma due to positive IgM for mycoplasma, though negative PCR. Start of treatment with prednisolone had a positive effect; however the problem with pain remained for a few weeks. In connection to the end of the prednisolone treatment in June 2009 (date not specified), the rheumatology consultant decided that the pericarditis and pleuritis were caused by mycoplasmal infection. The girl was then fully recovered, with no symptoms of chest pain, breathlessness or cough and on no medication. The reporter was wondering about the genesis of pericarditis and pleuritis and reported the event as a suspect adverse event following vaccination with GARDASIL. The previously essentially healthy girl was given the first dose of GARDASIL (batch number and route not reported) on unspecified date in December 2008. A few weeks following vaccination the girl experienced several upper respiratory infections, with symptoms of painful respiration. The case is linked to serious case E2010-00781 (WAES # 1002USA01232): same patient, who following vaccination with the third dose of GARDASIL (June 2009) experienced pulmonary embolism. Other business partner number included E2010-00777. The outc

Other Meds: Unknown

Lab Data: Mycoplasma PCR, ??09, negative; serum C-reactive protein, ??09, 71; serum Mycoplasma pneumoniae IgM Ab, ??09, positive

History: Upper respiratory tract infection; Painful respiration

Prex Illness:

Prex Vax Illns:

Vaers Id: **380402-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Jan-2010	18-Jan-2010	0	15-Feb-2010	16-Feb-2010	FR	WAES1002USA01073	16-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Anaphylactic shock, Respiratory arrest, Urticaria

Symptom Text: Serious case received from foreign Health Authorities under the reference number DHH-N2010-50099 on 03-FEB-2010. Case reported as serious (category: life-threatening), additional seriousness category: hospitalization. A 12 year old female patient with pollen allergy and house dust mite allergy were fully under control and had no dependencies to alcohol, tobacco or medication, had received the first dose of GARDASIL (batch number not reported) on 18-JAN-2010 via intramuscular route. There were no concomitant medications. The same day, 30 seconds after vaccination, she experienced an anaphylactic shock characterized by a facial urticaria and complete respiratory arrest. She received epinephrine via intramuscular route, as well as VENTOLIN pump (GSK, puff) and QVAR pump (UCB, puff). The patient was hospitalized for one night for observation. It was reported that the patient has fully recovered, without sequelae. Other business partner numbers include E2010-00793.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pollen allergy; House dust mite allergy

Prex Vax Illns:

Vaers Id: **380403-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Jun-2009	01-Oct-2009	122	15-Feb-2010	16-Feb-2010	FR	WAES1002USA01232	16-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pulmonary embolism, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a Health Authority (HA ref. 096248) concerning an 18 year old female was vaccinated with the third dose of GARDASIL (batch number and route unknown) on unspecified date in June 2009. HA reported pulmonary embolism (causality not reported) with onset in 2009, four months post vaccination (date unspecified). The girl was put on treatment with warfarin (mfr other). Coagulation investigation was without any remark and the pulmonary embolism was judged as unprovoked. It was not reported whether the patient was hospitalized or not for this event. The previously essentially healthy girl was given the first dose of GARDASIL (batch number and route not reported) on unspecified date in December 2008. A few weeks following vaccination the girl experienced several upper respiratory infections, with symptoms of painful respiration. The case is linked to serious case E2010-00777 (WAES # 1002USA01070): same patient, the second dose of GARDASIL, other AE. In connection to vaccination (date unknown), the girl experienced periods with fever, painful respiration and increased CRP (=71, Ref. <3). Findings (unspecified) of pericardial and plural liquid were make some weeks later which resulted in hospitalization. Diagnosis: pericarditis and pleuritis caused by mycoplasmal infection. The agency considered pulmonary embolism to be an other important medical event. Other business partner number included E2010-00781. The outcome is unknown. No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, ??Oct?09, coagulation investigation was without any remark

History: Upper respiratory tract infection; Painful respiration; Painful respiration; pleurisy; pericarditis; c-reactive protein increased; pericardial drainage test abnormal; pleural fluid analysis; mycoplasma antibody positive; fever

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380408-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Sep-2009	24-Sep-2009	0	15-Feb-2010	15-Feb-2010	AZ		15-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2905AA		Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B036BA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0652X		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Fainted following vaccine administration.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380426-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Feb-2010	11-Feb-2010	0	15-Feb-2010	15-Feb-2010	WA		16-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1538Y	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3048AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3250AA		Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1215Y		Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysphagia, Pruritus, Rash

Symptom Text: Rash & itching to bilat. arms and face with sensation of hard to swallow within 30 min. of injections of TDAP, HPV, MCV-4, HEP A, & VARICELLA.

Other Meds: CLARITIN prescribed 02/02/10 office visit

Lab Data:

History: No, pt. reports allergy to rosemary

Prex Illness: None, treated for rash in clinic

Prex Vax Illns:

Vaers Id: 380440-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Dec-2007	30-Jan-2008	48	15-Feb-2010	15-Feb-2010	OR		22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2826AA	0	Left leg	Intramuscular	
	HPV4	MERCK & CO. INC.	1063U	0	Right leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Abscess drainage, Abscess limb, Adverse drug reaction, Anxiety, Back pain, Depression, Dermal cyst, Diarrhoea, Disturbance in attention, Fall, Headache, Inappropriate schedule of drug administration, Infection, Joint sprain, Pelvic pain, Phonophobia, Photophobia, Purulent discharge, Rash generalised, Rash papular, Skin nodule, Tic, Traumatic brain injury

Symptom Text: Since receiving 1st dose of Gardasil, I started noticing a decline in my child's mental health. She has become depressed and has extreme difficulty concentrating. Shortly after receiving her 3rd dose of the vaccine, she started having stomach pains. These have continued to this date. We have had an ultrasound, CT scan, blood and urine work done, still no answers. ```2/18/10 Received PCPmedical records for 12/13/07 FINAL DX: Records reveal patient w/back pain, foot pain, warts on hands/knees. Back pain began s/p fall 8/07. RTC 1/8/08 w/abscess right thigh, I&D done w/significant amt of purulence drained. RTC 1/18/08 w/fine papular rash all over x 1 day. Dx w/probable drug reaction to sulfa. Tx w/antihistamines. RTC 1/25/08 w/worsened abscess right leg. States had lumps on leg for approx 6 mo then developed abscess. Exam revealed purulence. Dx w/probable sebaceous cyst w/secondary infection. Tx w/antibiotics. RTC 6/24/08 w/intermittent facial tics & throat clearing. Dx w/above avg anxiety thought to cause tics. Referred for counseling. RTC 1/21/09 w/abdominal pain. RTC 1/24/09 w/persistent lower abdominal pain, now w/diarrhea. Seen in ER 6/13/09 for fall w/HA, phono & photophobia. w/generalized HA w/photophobia. Seen in ER 11/21/09 s/p fall & hitting head. RTC 1/28/10 dx/w shoulder sprain & depression. RTC 2/11/10 for chronic low back pain & pelvic pain. Refrerred to GYN.

Other Meds:

Lab Data: ```2/18/10 Received medical records w/LABS: left thigh wound c/s - klebsiella. CT head WNL.

History: Sulfa drug allergies ```2/18/10 Received medical records w/PMH: acne. Received HPV #3 6/24/08, Lot # 1757U, IM, right thigh. No available info on HPV #2.

Prex Illness: No

Prex Vax Illns:

Vaers Id: 380445-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Feb-2010	11-Feb-2010	1	15-Feb-2010	16-Feb-2010	IA		15-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chorea, Cogwheel rigidity, Dizziness, Grip strength decreased, Headache, Hypoaesthesia, Peripheral coldness, Reflex test abnormal, Tremor

Symptom Text: GARDASIL #3 on 2/10/10. R arm tremors, headache, dizziness began 2/11/10. ```PCP visit received 02/16/10 for DOS 02/11/10. Pt c/o R arm tremors, hand cold. On exam: poor coordination, decreased strength. Assessment: cogwheel rigidity R arm. PCP visit 02/15/10. Pt continues R arm tremors, dizziness worsened, HA. Assessment: R arm tremors, dizzy, HA. ```H&P and DC summary received 02/18/10 for DOS 02/11/10-02/12/10. DX: non organic R UE tremor. Pt admitted for observation and lab work. Pt c/o acute onset of R arm. On neuro exam: fine tremor and numbness RUE, biceps, R hand cold to touch, decreased R hand grip, no RUE triceps/brachioradialis reflex. Dr considered these tremors as not related to stressors/psychological. Impression: RUE chorea. All tests were negative. Pt discharged in good condition.

Other Meds: None

Lab Data: Normal MRI brain/spine; normal EEG ```Labs and DX studies: 02/12/10 lumbar and brain MRI normal, EEG normal.

History: ```PMH: 3yrs ago h/o BLE weakness due to viral illness. Allergies: NKDA.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380458-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Feb-2010	15-Feb-2010	0	16-Feb-2010	16-Feb-2010	TX		16-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3013AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope

Symptom Text: Pt. had Hgb checked in room-then was administered MCV4 and HPV vaccines. Shortly after reving vaccines was talking-then fainted fell off exam table and fell onto floor hitting her head. Coc-20 sec. 911 called. Sent to ER-DC'ed after cat scan.

Other Meds: None

Lab Data: CT of head

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 380469-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Oct-2009	19-Oct-2009	6	16-Feb-2010	17-Feb-2010	IA	WAES0912USA02484	15-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0311Y	1	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Decreased appetite, Disturbance in attention, Fatigue, Headache, Lethargy, Migraine, Nausea, No reaction on previous exposure to drug, Performance status decreased, Ultrasound abdomen normal, Vomiting

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who in August 2009, was vaccinated with the second dose of GARDASIL. According to the physician, the patient developed headaches and fatigue after the second dose of GARDASIL. At the time of the report the patient had not recovered. The patient sought medical attention by an office visit. Follow up information has been received from the physician who indicated that the patient was a female student with no known drug allergies/reactions and no pertinent medical history who on 11-AUG-2009 was vaccinated with her first dose of GARDASIL (LOT # 659054/0311Y) intramuscularly into her left arm at 14:10 pm and on 13-OCT-2009 was vaccinated with her second dose of GARDASIL (LOT # 659054/0311Y) intramuscularly into her left deltoid at 13:50 pm. No illnesses were reported at the time of vaccination. It was reported that on approximately 19-OCT-2009 the patient began experiencing headaches, daily nausea, loss of appetite, vomiting, lethargy and inability to concentrate. At the time of the report the patient had not recovered. Diagnostic laboratory tests were performed included a CT scan and the US of abdomen reportedly as normal limits, other diagnostic tests were within normal limits and other labs and hospital visits per other physician. The reporting physician considered headaches, daily nausea, loss of appetite, vomiting, lethargy and inability to concentrate to be disabling/incapacitating events since the patient missed many days at school (additional information was not legible). Additional information is not expected. ```PCP notes received 02/17/10 for DOS 11/24/09. Pt c/o nausea, HA and poor performance at school due to these sx. Tx of Amitriptylin relieved HA. Pt still had nausea. ```PCP notes received 02/17/10 for DOS 12/02/09. Pt referred for Pediatric GI consult. On 02/02/10, Pt c/o ongoing HA, nausea and unable "to function" and missing school. Pt's parent reported that Pt was undergoing neurological consult, bu

Other Meds: Unknown

Lab Data: computed axial, NL normal limits; diagnostic laboratory, within normal limits ```Labs and DX studies: 12/01/09 abdominal U/S normal. CT of brain negative. Celiac study negative.

History: ```PMH: headaches. Allergies: Promethazine HCL.

Prex Illness:

Prex Vax Illns:

Vaers Id: **380471-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	25-Jan-2010	25-Jan-2010	0	16-Feb-2010	17-Feb-2010	FR	WAES1002USA01339	17-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Crying, Headache, Immediate post-injection reaction, Listless, Pallor, Pulse pressure decreased, Somnolence, Syncope, Thirst

Symptom Text: Initial case was reported as serious on 04-FEB-2010 by Health Authority (HA ref. NO-NOMAADVRE-FHI-2010-9852, FHI-10/325). It was reported that a 12 year old female patient suffering from DIGEORGE'S syndrome who on 25-JAN-2010 was vaccinated with the first 0.5ml dose of GARDASIL. No information on any medical treatment for DIGEORGE'S syndrome was reported. HA coded convulsion, pulse weak, syncope, facial pallor, crying, listlessness, sleepiness and thirst (causalities possible) with onset on the day of vaccination, 25-JAN-2010. Within minutes post vaccination the girl developed weak pulse, thirst, listlessness and sleepiness while crying, facial pallor, syncope and convulsion appeared already after 1 minute following vaccine administration. The outcome for pulse weak, syncope and convulsion is recovered while unknown for thirst, listlessness, crying, facial pallor and sleepiness. According to the HA, the event could possibly be consistent with a vasovagal reaction. Convulsion, pulse weak, syncope, facial pallor, listlessness, sleepiness and thirst were considered to be other important medical events by the reporter. Other business partner number included: E2010-00775. Case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: DIGEORGE'S syndrome

Prex Vax Illns:

Vaers Id: 380472-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Oct-2009	02-Nov-2009	27	16-Feb-2010	17-Feb-2010	FR	WAES1002USA01385	17-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Dizziness, Headache, Intracranial venous sinus thrombosis

Symptom Text: Case received from the Health Authorities on 04-FEB-2010 under the reference number GR-EOF91639 and received under the the reference number SPV10005: On 06-OCT-2009 a 14-year-old female patient received the second dose of GARDASIL (batch#, lot# not reported). Vaccination was performed by a paediatrician. From 02-NOV-2009, she presented with intense nascent headache and dizziness, and thrombosis of a brain venous sinuses. No relevant medical history or concomitant medications were reported. The patient was hospitalized from 04-NOV-2009 to 13-NOV-2009 after brain CT scan, the findings of which were suspect from thrombosis of venous sinuses was documented by MRI-MRV. Test for thrombophilia- vasculitis- neoplasia did not reveal any pathologic findings. The patient's condition was improved with immediate anticoagulant treatment. It was also reported that the patient was under pharmaceutical treatment with SINTROM for the next 6 months. The outcome was reported as "recovering/resolving". The Health Authorities initially received the report from a hospital physician (neurologist). The Health Authorities assessed the causal relationship between the reported reactions and vaccination as probably related. The seriousness criteria reported by the HA were "caused/prolonged hospitalization" and "life threatening". The HA coded the events "intense nascent headache", "intense nascent dizziness" and thrombosis of brain venous sinuses". Other business partner number included: E2010-00884. Additional information has been requested.

Other Meds: None

Lab Data: head computed axial tomography, 02?Nov09, suspect for thrombosis of venous sinuses; magnetic resonance imaging, 02?Nov09, diagnosis of thrombosis of venous sinuses; diagnostic laboratory test, 02?Nov09, thrombophilia- vasculitis- neoplasia

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380488-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Aug-2009	11-Aug-2009	0	16-Feb-2010	16-Feb-2010	FL		16-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0693Y	1	Left arm	Subcutaneously	
	HEPA	MERCK & CO. INC.	1604X	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local swelling, Skin warm, Throat irritation

Symptom Text: LOCAL SWELLING AND HOT TO TOUCH (LEFT ARM) FOLLOWED BY EPISODE OF THROAT ITCHING AND POSSIBLE TONGUE SWELLING. BENADRYL GIVEN BY PARENT. NO VISIT TO ER OR MEDICAL OFFICE.

Other Meds:

Lab Data:

History:

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380545-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	21-Apr-2009	22-May-2009	31	17-Feb-2010	18-Feb-2010	FR	WAES0906USA00463	18-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1172U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a gynecologist for GARDASIL, concerning a 25-year-old female patient (with child wish) who was vaccinated with the first dose of GARDASIL (lot # 11472U, batch # NH13130) on 24-FEB-2009 and was well tolerated. The patient was vaccinated with the second dose of GARDASIL vaccine (lot # 1172U, batch # NH13130) IM into the deltoid muscle on 21-APR-2009. Pregnancy test was positive on 19-MAY-2009. At that time the patient was in the 6th week of pregnancy. Last menstrual period was 10-APR-2009 (estimated delivery date was 15-JAN-2010). No adverse effect occurred at the time of reporting. Additional information received on 01-FEB-2010 which led to upgrade of the case to serious. It was reported that the patient had a spontaneous abortion on 22-MAY-2009. The patient's spontaneous abortion was considered an other important medical event. Case is closed. Other business partner numbers included: E2009-04325.

Other Meds: Unknown

Lab Data: beta-human chorionic gonadotropin (unsp), 19May09, positive pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 10Apr09)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380546-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Feb-2010	01-Feb-2010	0	17-Feb-2010	18-Feb-2010	FR	WAES1002USA01692	18-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ37700	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Convulsion, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a foreign Health Authority (case n. 111181) through local case # IT064/10. A 14 year old female was vaccinated on 01-FEB-2010 at 12:00; with the first dose of GARDASIL, (Lot # NJ37700, Batch # NK31720). On the same day, 30 seconds post-vaccination, she presented with a vasovagal syncope with convulsive crisis. The patient quickly regained her state of consciousness but did have any recollection of the event. Emergencies were called and she was sent to the ER where the diagnosis was: vasovagal syncope. The outcome was recovered on 01-FEB-2010. Both the reporter and the Health Authority considered the case as serious. To note, Health Authorities coded only syncope vasovagal and convulsive seizure. The adverse events of syncope vasovagal, convulsive seizure and amnesia transient were considered serious as other important medical events. This case was the linked case of cluster of 2 cases after GARDASIL, reported by the same physician with the same lot number NJ37700 batch number NK31720. Case linked with case E2010-00847. This case is closed. Other business partner included E2010-00846. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380572-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Feb-2010	17-Feb-2010	0	17-Feb-2010	17-Feb-2010	MA		17-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Felt dizzy in elevator leaving office, per mom almost fainted. Came upstairs. No syncope or vomiting. Laid down, given juice, observed, did fine.

Other Meds:

Lab Data: none

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380583-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Jan-2010	26-Jan-2010	0	17-Feb-2010	18-Feb-2010	IA		25-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3043AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0806Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site swelling, Injection site warmth

Symptom Text: A couple hours after VARIVAX injection given patient had a 3" diameter raised, hot area at the injection site per mom's report. Dr. was paged and prescribed Zyrtec 10 mg daily. They used ice pack to the area which also helped resolve her symptoms. The itching subsided and patient was better on 1/29/2010.

Other Meds:

Lab Data: Patient has asthma-exercise induced

History: None

Prex Illness: Urinary tract infection

Prex Vax Illns:

Vaers Id: **380589-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Jan-2010	Unknown		17-Feb-2010	18-Feb-2010	GA		18-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2923AA		Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB359AA		Unknown	Intramuscular	
	DTAP	SANOFI PASTEUR	U2472CA		Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	1164Y		Unknown	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B033BA		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0819Y		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: DTAP immunization given in place of TD. No adverse reactions from patient.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380599-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Jun-2009	13-Jun-2009	2	17-Feb-2010	18-Feb-2010	AR	AR10	15-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	09694	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Bronchitis, Cough, Dizziness, Fatigue, Headache, Influenza, Influenza serology negative, Loss of consciousness, Nervousness, Pain, Presyncope, Pyrexia, Sinusitis, Syncope, Tremor, Vertigo

Symptom Text: On 2nd day after 2nd GARDASIL arms & legs shaking unsure of which side. Now having c/o frequent passing out lasting ? 30 sec. to one minute but unsure how long. Has never timed them. Frequent headache & feeling shaky inside. Has seen Dr. several times but no diagnosis yet. ```02/18/10 received Pediatrician's records for 09/29/09-01/25/10 as dates of service. DX: Sinusitis, Bronchitis, Flu, Vasovagal syncope, Recurrent syncope, Prolonged complaint of tremors and HA's. Presented to Pediatrician's office with c/o of flu-like symptoms, ongoing body aches, non-productive cough, bilateral ear pressure and fever, Z-pack given. Flu screen negative. Multiple return pediatric office visits with bronchitis, persistent HA, fatigue, weakness, vertigo, dizziness and lightheadedness, tremors, fainting episodes lasting 15-30 secs. Scheduled for neuro consult.

Other Meds: None

Lab Data: ```02/18/10 received Pediatrician's records for 09/29/09-01/25/10 as dates of service. LABS & DIAGNOSTICS: Holter monitor wnl, EKG wnl.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380613-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Aug-2009	Unknown		17-Feb-2010	18-Feb-2010	TX		15-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	06714	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Complex partial seizures, Convulsion

Symptom Text: Seizure disorder after receiving GARDASIL shot on 8/12/09. ```02/19/10, 02/25/10 and 03/02/10 received Pediatrician's records and Ped's neuro records for 04/14-12/12/09 as dates of service. Dx: Complex partial seizures with and without secondary generalization-new onset. Presented to Pediatrician reporting seizure activity night before.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 380615-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		17-Feb-2010	18-Feb-2010	PA		18-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U	2	Right arm	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Endoscopy abnormal, Oesophagitis ulcerative, Pelvic pain

Symptom Text: Patient has Crohn's Disease. 2-3 weeks after each inj. she developed ulcerative esophogitis. 3 endoscopies proved it not to be viral etc. but could not prove Crohns. Before the last bout was over she developed pelvic pain - was ill thru 11/05.

Other Meds: REMICADE

Lab Data: Will be sent.

History: Crohn's

Prex Illness: Crohn's - Stable on REMICADE

Prex Vax Illns:

Vaers Id: **380675-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	16-Feb-2010	16-Feb-2010	0	18-Feb-2010	18-Feb-2010	NE		18-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1131X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Hyperhidrosis, Presyncope, Pyrexia, Restlessness

Symptom Text: pt reports HA in PM-restless noc-near syncope@0300-sweats chills fever.

Other Meds:

Lab Data: None

History: Amoxicillin

Prex Illness:

Prex Vax Illns:

Vaers Id: **380687-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Jul-2008	08-Jul-2009	362	18-Feb-2010	18-Feb-2010	--		18-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Epilepsy

Symptom Text: Following the injection of GARDASIL my daughter developed epilepsy, and so far various doctors are trying various anti-seizure medications to try and control the seizures, but are not successful. A healthy child after being given the second shot of vaccine 3-dose regimen developed seizure a few days later, which has now repeats at least once a month. The EEG results determined that several areas of the brain have been affected, and that no cure is possible.

Other Meds: First dose administered on 5/11/08 at the age of 16, then the second dose was given 2 months later. Third dose was never administered because the seiz

Lab Data: EEG results after each seizure are available.

History: No pre-existing conditions or problems

Prex Illness:

Prex Vax Illns:

Vaers Id: **380690-1** **Related reports:** 380690-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Jul-2009	Unknown		18-Feb-2010	18-Feb-2010	FL		16-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Anxiety, Asthenia, Body temperature increased, Convulsion, Decreased appetite, Dyskinesia, Fatigue, Headache, Lacrimation increased, Memory impairment, Nausea, Pain, Panic attack, Stress, Syncope, Vomiting

Symptom Text: Mother of client states client "has been having seizure since she got her HPV shots." ```3/12/10 ED Records and Pediatriac consultation received for dates of service 8/22/09 to 2/4/10. Dx: Panic attack, anxiety, Abdominal pain. Presents to ED after period of altered sensation of sudden onset, followed by a period of fainting (second episode, recovered without neurological deficit). On another occasion presented to ED with c/o abdominal pain, intensity 10/10, stabbing through to the back, then all over, accompanied by n&v as well as decreased appetite, temp of 101.1. Discharged to home. After having 3rd dose of Gardasil pt. developed a bad HA on the same day. 3 weeks later not feeling well, bad HA, hands clenched up, legs flailing out. Taken to hospital where they thought she was having a seizure. Neurologist thinks there is a stress relationship, maybe panic attacks. HA's last a long time, wipe pt. out, eyes glaze over, will not remember entire day after an episode. Very tired and in pain (arms, legs, back). Cannot do any heavy lifting.

Other Meds:

Lab Data: ```3/12/10 ED Records and Pediatriac consultation received for dates of service 8/22/09 to 2/4/10. Labs and diagnostics: Glucose 114 (H), ALT 9 (L), WBC 13.3 (H), MCHC 34.3 (H), PLT. 144 (L), Neut % 87.1 (H), Lymph % 5.6 (L), Neut # 11.

History: None at time of immunization. ```3/12/10 ED Records and Pediatriac consultation received for dates of service 8/22/09 to 2/4/10. PMH: Alopecia areata, tonsillectomy, adenoidectomy, chicken pox, shingles, thrush. Allergic to PCN, sulfa and e-mycin.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **380690-2** **Related reports:** 380690-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Jul-2009	08-Feb-2010	195	03-Mar-2010	03-Mar-2010	FL		03-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Clients mother states she thinks clients seizures started after daughter received her 3rd HPV - Client is receiving treatment from a private physician - as stated by mother.

Other Meds: none

Lab Data: unknown

History: allergies; PCN, erythromycin; Sulfa - as stated by mother.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **380740-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	25-Aug-2009	01-Oct-2009	37	18-Feb-2010	19-Feb-2010	WA		24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Unknown	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	500673P		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Convulsion, Death, Decreased activity, Fall, Headache, Hypertension, Hypoaesthesia, Injury, Loss of control of legs, Menstruation irregular, Oedema peripheral, Paraesthesia, Peripheral coldness, Sensory loss, Sudden unexplained death in epilepsy, Unresponsive to stimuli, Weight increased

Symptom Text: Patient received the HPV as well as the flu nasal spray on Aug 25th. I first declined getting her the vaccination but her doctor ensured me that it was safe. I had declined the same vaccination a year earlier at the downtown public health center. Patient was getting ready for school and was standing by her closet, and all of a sudden she fell, she lost total control of her legs. She went to school and could not engage in any of the activities because of the numbness in her legs and the swelling of her foot. She also, started to get a really bad headache. Days later she woke up out of her sleep complaining of a severe headache, which usually she gets if she has a seizure but she hadn't had a seizure this night. She continued to say she had not feeling in her foot and tingling feeling in her leg. After I examined her foot I noticed it was swollen. The next morning I called her doctors office and made her doctors appointment for Oct 23rd. During the month of October she had irregular periods. My daughter never made it to Oct 23rd, which as also her birthday. She passed on Oct. 17th, I found her cold unresponsive in her room at 7am, which I went in to wake her up to take her morning pills. ```Neurology records received 2/24/10. Service date 8/14/09. Assessment: Frontal lobe seizures. Patient presents for follow-up visit due to recent increase in seizure activity. Significant weight gain. High blood pressure. ```PCP medical records received 2/19/10. Service dates 5/21/08 to 10/23/09. PCP notes state N/S Injury 10/23/09. Expired 10/17/09. ```Death Certificate received 3/23/10. Cause of Death: Sudden Unexpected Death in Epilepsy (SUDEP).

Other Meds: Trileptol and Keppra

Lab Data: ```LABS and DIAGNOSTICS: CBC - WBC 4.5 K/mm3 (L) Lymphocytes 44.3% (H) Monocytes 13.5% (H). ALT 43 U/L (H).

History: Patient had a pre-existing seizure disorder which she was on trileptol and Keppra to control the seizures. ```PMH: Born 36 1/2 weeks gestation. Feeding difficulties at birth. Seizures.

Prex Illness: My daughter had a seizure disorder that came on with her periods.

Prex Vax Illns:

Vaers Id: 380750-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Sep-2008	08-Sep-2008	0	18-Feb-2010	19-Feb-2010	FR	WAES1002USA01872	19-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0583U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Activities of daily living impaired, Amenorrhoea, Asthenia, Bedridden, Decreased activity, Fatigue, Gait disturbance, Headache, Hyperhidrosis, Malaise, Muscle fatigue, Muscular weakness, Myalgia, Post viral fatigue syndrome

Symptom Text: Information was obtained on a request by the company from the agency via a Public Case Details form concerning a 16 year old female who on 08-SEP-2008 was vaccinated with a dose of GARDASIL (batch number J2896, lot number 657872/0583U). On 08-SEP-2008, after second dose of GARDASIL the patient experienced generalized muscular weakness, severe headache-could not participate in sports at school. The next 5-6 weeks the patient experienced severe and continual headaches, muscle pain and weakness to the extent that the patient had to be carried to the toilet and was bed-bound. The mother also reported that student did not menstruate at all in between her first and second dose of GARDASIL. The mother also commented that the student had noticed "that she was sweating a lot" between dose 1 and dose 2 of GARDASIL. On 03-JUN-2009 the patient was still unwell and was experiencing the same symptoms, (severe headaches, muscle fatigue, has difficulty walking due to weakness) and extreme fatigue. The patient had not been able to return to school as too unwell. The patient was hospitalized for 1 week under the care of immunologist who diagnosed the patient with "post viral fatigue". The patient had been referred to a clinic for ongoing reaction with a physiologist and psychologist. At the time of reporting on 21-SEP-2009, the patient had not recovered. The agency considered that muscular weakness, amenorrhoea, fatigue, headache and hyperhidrosis were possibly related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **380751-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Jan-2007	01-Feb-2007	14	18-Feb-2010	19-Feb-2010	FR	WAES1002USA01801	19-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Idiopathic thrombocytopenic purpura, Iron deficiency anaemia, Platelet destruction increased

Symptom Text: Information was obtained on request by the company from the agency via a public case details form concerning a 19 year old female patient with no significant past medical history who approximately two weeks before the onset date of the symptoms, on approximately 18-JAN-2007 was vaccinated with the second dose of GARDASIL (Lot not reported). On 01-FEB-2007 the patient experienced idiopathic thrombocytopenic purpura (ITP), antinuclear antibody positive and iron deficiency anaemia. The patient presented with iron deficiency (Hb 10.1g) and her platelet count was 35. Her bone marrow showed a picture consistent with ITP and peripheral platelet destruction. On an unspecified date, the patient's platelet count fell to 5. The patient antibody to nuclear antigens (ANA) was positive to a titer of >1280 with a speckled pattern. The rheumatoid factor was borderline at 21; the extractable nuclear antibodies (ENA) and DNA binding were negative. The patient was treated with oral corticosteroid and responded to the treatment, but the thrombocytopenia recurred when the therapy was weaned. Subsequently the patient was treated with rituximab (on clinical trial) and has remained in hematological remission. On 09-OCT-2009 the patient had recovered. The agency considered that idiopathic thrombocytopenic purpura, antinuclear antibody positive and iron deficiency anaemia were possibly related to therapy with GARDASIL. Idiopathic thrombocytopenic purpura, antinuclear antibody positive and iron deficiency anaemia were considered to be immediately life-threatening by the agency. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: bone marrow biopsy, ITP and peripheral platelet destruction; diagnostic laboratory test, DNA binding was negative; extractable nuclear antigen ab, negative; platelet count, 35; platelet count, subsequently fell to 5; serum ANA, positive a t

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380752-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-May-2007	Unknown		18-Feb-2010	19-Feb-2010	FR	WAES1002USA01717	19-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Affect lability, Aggression, Blunted affect, Depressed mood, Hallucination, auditory, Ideas of reference, Loss of consciousness, Mood altered, Paranoia, Psychotic disorder, Selective mutism, Social avoidant behaviour, Vaginal haemorrhage

Symptom Text: Information was obtained on request by the company from the agency via a public case details form concerning a 12 year old female who was given GARDASIL in May 2007 (reported on 15-MAY-2007), October 2007 and August 2008. In 2007, the patient became moody and erratic with ? psychotic episodes. Temporal relationship with GARDASIL in 2007 not known. In August 2008 the patient presented blackouts, withdrawn, aggression (verbal), labile mood. Blunted affect, paranoia, ideas of reference, auditory hallucinations, selective mutism. Depressed. Blood in underwear. Episodes of psych disturbance occurred at the time of the menstruation. The patient received treatment at a psychiatric hospital. At the time of the report the patient had not recovered from psychotic disorder. The reporter felt that causality of psychotic disorder with GARDASIL therapy was possible. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **380753-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Jan-2010	14-Jan-2010	0	18-Feb-2010	19-Feb-2010	FR	WAES1002USA01713	19-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypotension, Syncope

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-722099341) concerning a 14 year old female who on 14-JAN-2010 was vaccinated with a dose of GARDASIL (batch number, lot number and site not reported) by intramuscular route. It was reported that after vaccine administration, the patient suffered a dizziness, hypotension and syncope. She was recovered quickly. On the Health Authority report only arterial hypotension and syncope were coded. Start and stop date for arterial hypotension and syncope were reported (14-JAN-2010). Dizziness was not coded. Case reported as serious by the Health Authority with other medically important condition as criteria. However, according to the report, the reporter described the adverse event as mild. Case is closed. Other business partner numbers included: E2010-00873.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380754-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2010	19-Feb-2010	TX	WAES1002USA01521	19-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Multiple sclerosis, Retinal disorder

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the third dose of GARDASIL on an unspecified date. After receiving the vaccination the patient had been experiencing passing out periodically. The patient had also developed "scleroma in retinal" which was indicative of multiple sclerosis (MS). At the time of the report, the outcome was unknown. Upon internal review, multiple sclerosis was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380755-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
36.0	F	Unknown	Unknown		18-Feb-2010	19-Feb-2010	--	WAES1002USA01520	19-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervix carcinoma, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a nurse practitioner concerning a 36 year old female. The patient told the nurse practitioner that she was vaccinated with GARDASIL at the age of 12 years (approved for marketing on 08-JUN-2006) and she developed cervical cancer at the age of 36 years. At the time of the report, the outcome was unknown. Upon internal review, cervical cancer was determined to be an other important medical event. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380756-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	15-Sep-2006	15-Sep-2006	0	18-Feb-2010	19-Feb-2010	KS	WAES0612USA01320B1	19-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Intramuscular	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Tachycardia foetal

Symptom Text: Information has been received from a health professional for GARDASIL, a Pregnancy Registry product, concerning a female baby. On 15-SEP-2006 the baby's 17 year old mother with no known allergies was vaccinated IM with the first dose of GARDASIL (lot# 653735/0688F) in the right deltoid. On 11-OCT-2006, the baby's mother had a positive urine pregnancy test. It was reported that the mother had previously had a negative serum pregnancy test on 17-JUL-2006. The mother's last menstrual period (LMP) was 15-AUG-2006. Subsequently the baby experienced fetal tachycardia. On 04-JUN-2007 the baby was delivered with no congenital anomalies by cesarean section. The baby was healthy and normal. Estimated gestational age at delivery was 38 weeks, 1 day. The reason for the cesarean section was "unrelieved pain". The mother and baby were both discharged on 11-JUN-2007. The reason for the extended hospitalization was unknown. The mother's experience has been captured in WAES 0612USA01320. The event of fetal tachycardia was previously reported in WAES 0612USA01320. Attempts to obtain additional information regarding the infant have been unsuccessful. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 380757-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Feb-2010	03-Feb-2010	2	18-Feb-2010	19-Feb-2010	AZ	WAES1002USA01239	23-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Basal ganglia infarction, Drug abuse, Dyspnoea, Facial palsy, Gait disturbance, Hemiparesis, Hypoaesthesia, Ischaemic stroke, Rash, Sensory loss, Vasospasm

Symptom Text: Information has been received from a medical assistant concerning a 19 year old female patient with allergy to latex and sulfonamides and no medical history who on 01-FEB-2010 was vaccinated with the first 0.5 ml IM dose of GARDASIL (lot #662304/1013Y). Concomitant therapy included YASMIN. On 03-FEB-2010, the patient developed shortness of breath, numbness on the left side of body, and a rash on her chest. The patient was admitted to a medical center on 03-FEB-2010 for initial evaluation and then transferred to another hospital. A magnetic resonance imaging of the brain was performed which revealed a "mini-stroke". The medical assistant added that the physicians at that hospital did not feel the adverse events were related to GARDASIL. At the time of reporting, the patient was recovering from the adverse events. Follow up information received on 09-FEB-2010 from the medical assistant reported that the patient received no other vaccines at the time of the GARDASIL vaccination. The events were not disabling nor life threatening. It was planned that the GARDASIL series would continue. Additional information has been requested. ```2/19/10 Received hospital medical records for 2/4-2/8/2010. FINAL DX: right sided weakness & numbness secondary to ischemic stroke, specifically left basal ganglia infarct likely secondary to methamphetamine induced vasospasm. Records reveal patient experienced acute onset of right sided extremity weakness, right facial droop & numbness/decreased sensation right body. Had been transferred from outlying ER for higher level of care. Tx w/steroids & ASA. Improved. Able to transfer & ambulate short distances w/max assist of 2. Transferred to neurorehab. ```2/19/10 Received ER medical records of 2/3/2010. FINAL DX: CVA Acute onset weakness began approx 3 hr prior to ER. States had rash on chest area s/p vaccination but resolved when seen in ER. ```2/19/10 Received GYN medical records for 12/2/09-2/5/10. FINAL DX: ASCUS, HPV-DNA(+), yeast infection.

Other Meds: YASMIN

Lab Data: Magnetic resonance, 02/03/10, brain: mini-stroke ```2/19/10 Received hospital medical records w/LABS: CT head WNL. MRI brain & spine c/w acute ischemic stroke. Urine tox screen (+) methamphetamine. MRA head/neck WNL. TEE abnormal w/s

History: ```2/19/10 Received hospital medical records w/PMH: congenital cyst in neck closed at age 12. ```2/19/10 Received ER medical records w/PMH: Allergy: sulfa, latex. ```2/19/10 Received GYN medical records w/PMH: Pap smear abnormal, (+) high risk HPV. Colposcopy. Dysmenorrhea. Oral contraceptives. Smoker. Acne.

Prex Illness: Latex allergy; Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380768-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Feb-2010	12-Feb-2010	0	18-Feb-2010	19-Feb-2010	IN		15-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	13184VFC	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site mass

Symptom Text: 2x2 cm. indurated - non-tender lump (R) deltoid. No erythema.

Other Meds: None

Lab Data: None

History: PCN allergy

Prex Illness: None

Prex Vax Illns:

Vaers Id: **380798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Feb-2010	18-Feb-2010	0	19-Feb-2010	19-Feb-2010	VA		19-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	14460	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash erythematous, Rash pruritic, Tenderness

Symptom Text: red, pruritic, tender rash which started on the back and started spreading. no dob, no sob, no dyspnea

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **380810-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
-0.7	M	01-Feb-2009	28-Feb-2009	27	19-Feb-2010	22-Feb-2010	OR	WAES0907USA00684B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caput succedaneum, Congenital naevus, Drug exposure during pregnancy, Jaundice neonatal, Ocular icterus, Strabismus

Symptom Text: Information has been received from a physician via medical records concerning a male infant whose 25 year old mother with a history of 1 pregnancy and 1 live birth who was vaccinated IM with a first 0.5 ml dose of GARDASIL. The physician believed that the vaccine was given two weeks before the mother found out she was pregnant. Her LMP was 28-FEB-2009 (estimated delivery date was 05-DEC-2009). Ultrasound performed on 31-JUL-2009 showed normal result. On 24-NOV-2009 the mother was admitted for delivery. On 25-NOV-2009, at 08:20, the mother delivered a normal male neonate via spontaneous vaginal delivery. The baby's birth weight was 7 pounds and 14.25 ounces, length was 20 inches, chest circulation was 13.25 and head circulation was 13.5. The Apgar score was 9 at 1 minute and 9 at 5 minutes. The baby passed the hearing screen. Physical examination showed Mongolian spots sacrum, mild caput molding, positive bilateral retinal reflex, regulator rhythm and rate, no murmur, descended testes and no hip dislocate. On 26-NOV-2009 the mother and the baby were discharged from the hospital and discharge examination showed the baby had jaundice face. On 30-NOV-2009 the baby was seen for a newborn check. The baby had breast feeding, using Similac formula with iron. Physical examination showed skin jaundice (to xiphoid) and slight icteric in eyes. The assessment was healthy newborn and continued the current feeding regimen. On 22-DEC-2009 the baby was seen for a well child visit. Baby's father complained of possible cross eyed of the baby. Physical examination showed no significant strabismus. The doctor's assessment was normal occasionally strabismus and expected resolution over the next few months. On 26-JAN-2010 the baby was seen for a well child visit and physical examination revealed no abnormalities. The doctor's assessment was healthy 2 month old male baby. At the visit, the baby received the first dose of PED/ADOL-PRESERV FREE, pneumococcal and rotavirus, pentavalent RV5. Mongolian spots sacrum was considered a congenita

Other Meds: Unknown

Lab Data: Unknown

History: Appendicitis; Appendicectomy

Prex Illness:

Prex Vax Illns:

Vaers Id: **380811-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Feb-2010	01-Feb-2010	0	19-Feb-2010	22-Feb-2010	FR	WAES1002USA01694	22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ37700		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Memory impairment, Syncope, Trismus

Symptom Text: Information has been received from a Health Authority (case No. 111185) through (local case No. IT065/10). Initial report received on 05-FEB-2010. This case is the linked case of a cluster of 2 cases after GARDASIL vaccination, reported by the same physician with the same lot #NJ37700 and batch #NK31720. An 11 year old female with no previous medical history, was vaccinated on 01-FEB-2010 at 12:35 pm, with the first dose of GARDASIL vaccine (lot # NJ37700 and batch # NK31720). On the same day, 30-40 seconds post-vaccination, she presented with a vasovagal syncope with convulsive crisis and facial trismus. The patient quickly regained her state of consciousness but did not have any recollection of the event. Emergencies were called and she was sent to the ER where the diagnosis was: vasovagal syncope. The final outcome was not reported. The seriousness of the event was not defined by either the reporter or the HA. To note, Health Authorities coded syncope vasovagal, convulsive seizure and trismus. Upon internal review, syncope vasovagal, convulsive seizure and trismus were determined to be an other important medical event. The case is closed. Other business partner number included E2010-00847. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380813-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-Feb-2010	22-Feb-2010	FR	WAES0909USA00317B1	22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal disorder

Symptom Text: Information was obtained on request by the company from the agency via public case details form and and from a professor concerning a female who received GARDASIL intramuscularly early in her pregnancy. Subsequently, the patient gave birth to a female baby who experienced tracheo-oesophageal fistula. At the time of reporting, the outcome of the patient was unknown. The agency considered that tracheo-oesophageal fistula was possibly related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380814-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Feb-2010	19-Feb-2010	1	19-Feb-2010	19-Feb-2010	TX		22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	14874	0	Left arm	Intramuscular	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500853P	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysphagia, Erythema, Swelling face, Wheezing

Symptom Text: Facial swelling with erythma no SOB, wheezing, swallowing difficulty, pt. give Benedryl & prednisolone PO. Observed in office for 15 minutes, no further symptoms developed, slight improvement noted.

Other Meds:

Lab Data: none

History: none known

Prex Illness: none

Prex Vax Illns:

Vaers Id: **380836-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	22-Dec-2009	Unknown		19-Feb-2010	22-Feb-2010	MA		22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Genital rash

Symptom Text: after i took i got the shot gardisal a month later i started to get bumps around my genitals.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **380847-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
31.0	F	05-Sep-2009	Unknown		20-Feb-2010	22-Feb-2010	--		22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ18540	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abortion spontaneous, Dizziness, Drug exposure during pregnancy, Inappropriate schedule of drug administration, Menstruation irregular, Migraine, Nausea, Pain

Symptom Text: I was suffering from dizziness, nausea, frequent body and abdominal pain, and migraine for past 4-5 months but was not aware that this is because of the worst effect of this GARDASIL. I have not started any treatment yet. I already had 2 shots and final was due on 6th Mar 2010. I am also suffering from irregular monthly cycle after my miscarriage had on 8th Mar 2009. Still I am having same problem and taking Femilon as per Doctor's recommendation. I am not sure is this also because of this GARDASIL?

Other Meds:

Lab Data:

History: Hepatitis B, Dust allergy

Prex Illness: I was taking calcium and iron tablets during this vaccination. The 2nd shot I took on 5th Sep 2009 at 7PM. I first 2 shot abroad

Prex Vax Illns:

Vaers Id: 380852-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Nov-2008	19-Dec-2008	24	21-Feb-2010	22-Feb-2010	WI		22-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650K	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Condition aggravated, Convulsion, Dyskinesia, Gliosis, Inflammation, Nausea, Partial seizures, Vomiting

Symptom Text: sudden onset of stomachache, nausea and vomiting and multiple (10 plus) seizures ```PCP visit received 02/22/10 for DOS 12/20/08. Pt presented for physical and Pap. Pt got first dose of Gardasil. Pt was started on OC and risks of decrease of Lamictal effectiveness were discussed. ```DC summary received 03/15/10 for DOS 12/26/08-12/27/08. DC DX: nonepileptic seizures. Pt c/o seizures in BLE and BUE, jerking BLE. Tx: Diazepam. Pt reported having multiple daily sz episodes for 5 days prior to hospitalization. Pt kept for observation. EEG showed R central parietal maximal spike. Lamictal was increased, Trileptal decreased. Pt discharged home in stable condition. ```PCP visit received 02/26/10 for DOS 02/12/10. Pt s/p urgent R focal epilepsy surgery in Feb '09. pt with gliosis and inflammation. Pt with residual L UE mild weakness. SZ had stopped. Phenobarbital decreased.

Other Meds: Trileptal

Lab Data: hematology, head CT, MRI, medication levels, ```Labs and DX studies: EEG abnormal.

History: previously healthy, past medical history of epilepsy diagnosed at age 8 and well controlled on oral antiepileptic drugs ```PMH: epilepsy for 9 yrs, OC. Allergies: none.

Prex Illness: none noticed directly after receiving vaccine, however on December 19th, 2008 patient began having multiple seizures and was see

Prex Vax Illns:

Vaers Id: **380869-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Feb-2010	01-Feb-2010	0	19-Feb-2010	22-Feb-2010	FR	WAES1002USA02055	22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1695U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cyanosis, Dizziness, Headache, Nausea, No reaction on previous exposure to drug

Symptom Text: Information has been received from a gynaecologist concerning a 14 year old female patient who on 24-Nov-2009 was vaccinated with the first dose of GARDASIL which was well tolerated. On 01-Feb-2010 the patient was vaccinated with the second dose of GARDASIL (lot # 1695U, batch NH25730) IM into upper arm. The same day the patient developed cyanosis of hand and toes, headache, dizziness and nausea. she was hospitalized for 3 to 4 days and recovered on an unspecified date. The patient had suffered from abdominal pain before vaccination of the second dose of GARDASIL (onset not reported). The reporter felt that cyanosis, headache, dizziness and nausea were possibly related to GARDASIL. Other business partner number included: E2010-00938. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Abdominal pain

Prex Vax Illns:

Vaers Id: **380870-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Nov-2009	01-Dec-2009	30	19-Feb-2010	22-Feb-2010	FR	WAES1002USA02274	22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1648U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Autoimmune disorder

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with no relevant personal nor familiar medical history, no stress or emotional shock and no ongoing treatment; who in November 2009, was vaccinated with the first dose of GARDASIL (batch number NH43700, lot number 1648U). One month later, she experienced severe alopecia. She had not recovered when she received the second dose of GARDASIL (batch number not reported) on an unspecified date. After the second injection, she lost all her hair. Blood work-up was normal. She was seen in hospital in a specialized hair clinic, where they observed atrophy of hair bulbs, which was described as an autoimmune-induced phenomena. No scalp biopsy was performed. At the time of reporting, the patient had not recovered and was still on unspecified treatment. The physician specified that she would not proceed with the the third injection of GARDASIL vaccine. Alopecia was considered to be an other important medical event. Other business partner numbers include E2010-00991. No further information is available.

Other Meds: none

Lab Data: Hematology. blood work-up: normal

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380888-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Feb-2010	12-Feb-2010	0	22-Feb-2010	22-Feb-2010	PR	PR-10-03	22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	2	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dizziness, Pallor, Visual impairment

Symptom Text: AFTER RECEIVING VACCINATION THE PATIENT BEGAN FEELING DIZZY, COULDN'T SEE WELL THROUGH HER RIGHT EYE, FELT CHILLS. SHE APPEARED PALE 25 MINUTES AFTER VACCINATION. WAS IN OBSERVATION FOR A WHILE UNTIL SHE BEGAN FEELING BETTR AND LESS PALE.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **380910-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	05-Feb-2010	05-Feb-2010	0	22-Feb-2010	22-Feb-2010	TX		22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site papule

Symptom Text: Rash right upper extremity upper arm & anterior forearm-papule, dull red, small crops.

Other Meds:

Lab Data:

History: Allergic rhintis

Prex Illness: Vaginitis/ Depression

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380919-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	11-Feb-2010	11-Feb-2010	0	22-Feb-2010	22-Feb-2010	CA		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2933A	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainting after vaccine.

Other Meds: ZOLOFT; NUVARING

Lab Data: None

History: Depression

Prex Illness: Depression

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380942-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Jan-2007	16-Jul-2007	187	22-Feb-2010	22-Feb-2010	CA		22-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0171U		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menorrhagia

Symptom Text: Patient claims since the 1st "GRDASIL" injection on 1/10/07 has been having heavy menstruation. (no other cause found).

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380968-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
34.0	F	21-Dec-2007	22-Dec-2007	1	22-Feb-2010	23-Feb-2010	FR	WAES1002USA01739	23-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Chronic fatigue syndrome, Inappropriate schedule of drug administration, Injection site mass, Injection site pruritus, Injection site swelling

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail concerning a 34 year old female patient who on 31-JUL-2007 and on 21-DEC-2007 was vaccinated with a dose of GARDASIL (route and lot # unknown) respectively. It was reported that in December 2007, the patient experienced permanent itching and swelling at the site of injection. It was reported as a lump under the skin that increased in size when she scratched it. It was reported that in march 2008, the patient presented the symptoms of Chronic Fatigue Syndrome and she was officially diagnosed by 2 different specialists in October 2008 after diagnosis by elimination. It was reported that there was no treatment from Chronic Fatigue Syndrome and that a cortisone cream for injection site was prescribed to try stopping itching but it did not work. It was reported that by September 2009 all the symptoms were still active. The reporter felt that chronic fatigue syndrome and injection site reaction were possibly related to therapy with GARDASIL. Chronic Fatigue Syndrome and injection site reaction were considered to be disabling. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380969-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Jan-2009	21-Jan-2009	0	22-Feb-2010	23-Feb-2010	FR	WAES1002USA01794	23-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Dysarthria

Symptom Text: This case is linked with case E2010-00923 (WAES#1002USA02408) (same patient, same product, different doses). Information has been received from the Foreign Health Authorities (Ref: ES-AGEMED-707202240) concerning a 15 year old female patient who on 21-JAN-2009 was vaccinated with the second dose of GARDASIL (batch number not reported, site of administration not reported) by intramuscular route. It was reported that on the same day of vaccine administration, 21-JAN-2009, the patient presented with dysarthria and loss of vision. The patient recovered on the same date, 21-JAN-2009. It was reported that the patient suffered from cephalea since the administration of the first dose of GARDASIL (batch number, date, route and site of administration not reported) (case E2010-00923) (WAES#1002USA02408). The patient did not want to receive the third dose of vaccine due to adverse events. No further information was given. Case reported serious by the health authorities with other medically important condition as criteria. Case is closed. Other business partner number include E2010-00922.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Headache

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380971-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		22-Feb-2010	23-Feb-2010	FR	WAES1002USA02281	23-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Type 1 diabetes mellitus

Symptom Text: Information has been received from a physician concerning a 25 year old female patient with no relevant history reported, who "approximately 3 years before the report", in approximately 2007, was vaccinated with the first dose of GARDASIL (route and lot # unknown). Subsequently, on an unspecified date, the patient experienced type 1 diabetes. The remaining doses were not administered by the reporting physician, who considered that the event was related to vaccination. The outcome was not reported. Type 1 diabetes mellitus was considered to be an other important medical event by the physician. Other business partner numbers include E2010-00973. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **380998-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	09-Feb-2010	09-Feb-2010	0	22-Feb-2010	23-Feb-2010	NH		23-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None stated

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381019-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-Feb-2010	21-Feb-2010	2	22-Feb-2010	23-Feb-2010	SC		23-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Back pain, Diarrhoea, Dizziness, Fatigue, Headache, Myalgia, Nausea, Night sweats, Pain, Proctalgia, Pyrexia

Symptom Text: Severe diarrhea, headaches, nausea, could not even keep water down, dizziness, night sweats, muscle and body pain, fever,tiredness, weakness, back pain,rectal pain

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381030-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	22-Feb-2010	22-Feb-2010	0	23-Feb-2010	23-Feb-2010	ME		23-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Nausea

Symptom Text: Dizzy, nauseated, abdominal pain. Lasted about 2 hours. Pt. monitored in the offfice. No treatment given.

Other Meds: Ortho Tri-Cyclen

Lab Data: None

History: NA

Prex Illness: sore throat

Prex Vax Illns:

Vaers Id: 381031-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Jan-2010	08-Feb-2010	10	23-Feb-2010	23-Feb-2010	PR	PR1005	18-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y		Unknown	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP065AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	43046AA		Unknown	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037AA		Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Gait disturbance, Hyperreflexia, Myelitis transverse, Pain, Tremor

Symptom Text: BILATERAL TREMOR, PAIN, WEAKNESS, HYPEREFLEXIA IN BOTH LEGS. GAIT AFFECTED. WAS HOSPITALIZED. ```2/25/10 Hospital records and discharge summary received for dates of service 2/12/10 to 2/19/10. DX: Transverse myelitis, anxiety disorder Presented with lower extremity involuntary movements, tremors, gait affected, treated with Solumedrol x 5 days with significant improvement. Discharged stable under parents care.

Other Meds:

Lab Data: CBC, BMP, CT, MRI. ```2/25/10 Hospital records and discharge summary received for dates of service 2/12/10 to 2/19/10. Labs and diagnostics: MRI (thoracic) w/contrast-unremarkable.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **381051-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		23-Feb-2010	24-Feb-2010	SD	WAES1002USA01619	24-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a physician concerning a 13 year old female who in approximately 2010, "recently", was vaccinated with the second dose of GARDASIL 0.5 ml (route and lot # not reported). On the following evening during a basketball game, the patient had a syncope episode and the coach diagnosed it as seizure. The patient was taken to emergency room but not hospitalized. It was reported that the patient's event was improved subsequently but the final outcome was unknown. All attempts to obtain follow up information has been unsuccessful. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **381052-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	01-Sep-2009	12-Feb-2010	164	23-Feb-2010	24-Feb-2010	--	WAES1002USA02597	24-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Haemorrhage, Inappropriate schedule of drug administration, Placental disorder

Symptom Text: Information has been received from a Nurse Practitioner, for the pregnancy registry for GARDASIL, concerning a 27 year old female patient, with depression, anaemia and allergy to CECLOR, BENADRYL, and ADVIL, who on 01-SEP-2009 was vaccinated with the first dose of GARDASIL (route and lot number not provided). Concomitant therapy included influenza virus vaccine (unspecified) and H1N1. On 01-SEP-2009, an urine pregnancy test was performed and was negative. The Nurse Practitioner stated that patient went to her office for urine pregnancy test on 12-OCT-2009 and it was positive. Early ultrasound performed on 14-OCT-2009, showed patient was 9.4 weeks pregnant at that time with an expected delivery date on 16-MAY-2010. On 12-FEB-2010 the patient, who was 27 weeks pregnant at that time, was hospitalized overnight, with bleeding which nurse practitioner stated was caused by a low lying placenta. The patient was treated with betamethasone (manufacturer unspecified) and released the next day. Bleeding issue was resolved. Additional information has been requested.

Other Meds:

Lab Data: Ultrasound, 10/14/09, 9.4 weeks pregnant; urine beta-human, 09/01/09, negative; urine beta-human, 10/12/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Depression; Anaemia; Allergic reaction to antibiotics; Drug hypersensitivity; Drug hypersensitivi

Prex Vax Illns:

Vaers Id: **381053-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Jan-2008	Unknown		23-Feb-2010	24-Feb-2010	FR	WAES1002USA02266	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0482U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Anxiety, Aphthous stomatitis, Asthenia, Ear pain, Fatigue, Headache, Nasopharyngitis, Oropharyngeal pain, Pain in extremity, Pharyngeal erythema, Pharyngitis, Pyrexia, Tonsillar disorder, Upper respiratory tract infection

Symptom Text: Information has been received from a consumer (mother of the patient) on 11-FEB-2010. It was reported that a 14 year old female patient was vaccinated with a third dose of GARDASIL (Lot # 1482U, Batch # NG09920) IM, into the upper arm on 20-MAY-2008. According to the mother, the patient developed fever, headache and pain in the injected arm the same day and recovered. Since a few weeks post vaccination, the patient experienced relapsing asthenia, common colds, fever, lassitude and "anxiety states" every 2 to 3 weeks. Clinical investigation showed no pathological findings, tropical diseases were ruled out. At the time or reporting, symptoms were ongoing. The family physician was contact by phone. He pointed out that he didn't see a causal relation to the vaccination. However on request he sent reports on findings from the OPDs of rheumatologic department and the department for tropical medicine. On 12-May-2009 and 16-JUN-2009 the patient presented at a rheumatological/immunological outpatient department. Medical history included relapsing fever up to 39 degrees C since February 2009 (in contrast to the information about onset given by the mother) bi weekly. Initially the fever had been associated to upper respiratory tract infections which stopped within an unspecified time . Fever lasted for 3 days each time. No previous relapsing infection nor further complaints, no arthralgia nor signs for arthritis, no diarrhea in patient's and patient's family history. The physical examination was normal. Blood count, CRP, hepatic and renal values, IgG and IgG subtypes and clinical chemistry were normal expect for marginal decreased ferritin (9.7 ng/ml). Anti-nuclear antibodies showed negative results. Values for EPSTEIN BARR VCA IgG antibodies 321 U/ml, EPSTEIN BARR VCA IgM antibodies <20.0 U/ml indicated a recent EBV infection but no evidence for a new primary infection. Cytomegalovirus IgM antibodies <15 U/m, Parvovirus B19 IgM antibodies 0.2 (reference region < 0.9). All examinations showed no evidence for "periodic feve

Other Meds: Unknown

Lab Data: Renal function study, normal; diagnostic laboratory test, ADNase B, 79.6; serum ferritin assay, 12May09, 9.7 ng/ml; temperature measurement, 12Jan10, 39.4 degrees C; body temp, ??Feb10, 39 degrees C; blood chemistry, normal; extractable nuc

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381063-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Nov-2009	05-Nov-2009	2	23-Feb-2010	23-Feb-2010	GA		23-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	1	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	500707P	0	Unknown	Unknown	
	FLU(H1N1)	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Pain in extremity

Symptom Text: Had immunizations Hep A, GARDASIL, IPV, MCV, MMR 9/30/09 1 month later had problems breathing at night and when exercising. Went to MD - given antibiotics and it cleared up. On 11/3/09 -received FLUMIST and H1N1, GARDASIL- 2days later 11/5/09 breathing problems returned went to Dr and got antibiotics but when did not clear the breathing problems up. Still has problems when exercising. Mom said also the afternoon she received immunizations on 11/3/09 client had pain on left thigh lasted a couple of days better now. I told mom to go back to the physician regarding difficulty breathing. No respiratory difficulty noted now.

Other Meds: None

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381064-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	04-Aug-2009	04-Aug-2009	0	23-Feb-2010	24-Feb-2010	FR	WAES1002USA01792	24-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Injection site swelling, Pyrexia, Vomiting

Symptom Text: Information has been obtained on request by the company from the agency via public case details form concerning a 21 year old female who on 04-AUG-2009 was vaccinated with the third dose of GARDASIL. The patient experienced massive local swelling at the injection site, intense fever and vomiting on the afternoon of receiving the third dose of GARDASIL. Two days after injection the patient was admitted to hospital and commenced on IV antibiotics. The patient was discharged two days later. The treating physician believed that there was a reasonable possibility that the events were related to the GARDASIL vaccine. The patient's outcome was unknown. The original reporting source was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **381083-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Feb-2010	17-Feb-2010	0	23-Feb-2010	23-Feb-2010	GA		23-Feb-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	SKBAHAVB334BA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	MSD1049Y	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	PMCU3011AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	SKBAC52B047BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Loss of consciousness, Muscle tightness

Symptom Text: Client in HD for vaccinations administered TDAP and Hep a in LD and HPV and MENACTRA in RD. Immediately after administration of HPV (last vaccine) client c/o feeling dizzy and then passed out. Her legs and arms constricted for about 30 seconds the client started coming back around. Father was positioned behind client and supported her head and upper body while I attempted to elevate head, provide cool cloths and request assistance from staff. Client was provided a coke and gradually resumed her pre shot color. After the incident which lasted about 15 minutes, the family advised us that this occurrence has happened once when she gave blood once when she had her ears pierced and once when she had her navel pierced.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **381184-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-May-2008	24-Aug-2008	90	24-Feb-2010	25-Feb-2010	FR	WAES1002USA01850	25-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cerebral haemorrhage, Dizziness, Educational problem, Inappropriate schedule of drug administration, Nervous system disorder, Neurosurgery, Tic

Symptom Text: Information has been obtained on request by the company from the agency via public case details form concerning a 14 year old patient who on 26-MAY-2008 was vaccinated with her second dose of GARDASIL. Three months after the second dose of GARDASIL, the patient developed dizziness and a cerebral bleed. It was also reported that the patient underwent emergency neurosurgery and was admitted to brain injury unit. There was a neurological deficit, facial tic and poor school performance after neurosurgery. It was also mentioned that 3 month for onset of cerebral bleed post vaccination was difficult to explain plus patient was given the third dose of GARDASIL 10 months after the second dose in approximately 26-MAR-2009 with apparently no adverse event. (Schedule of vaccination was not followed). At the time of the report the patient had not recovered. The reporting source considered the vaccination with GARDASIL to be possibly related to the cerebral haemorrhage and dizziness. This is an amended report. Serious criteria for cerebral hemorrhage was changed from no to yes for hospitalization. Narrative statement was changed from "went to the emergency neurosurgery brain injury unit" to "underwent emergency neurosurgery and was admitted to the brain injury unit". The primary reporting source was not provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381211-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Oct-2009	Unknown		24-Feb-2010	24-Feb-2010	NY		25-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671V		Unknown	Unknown	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500762P		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: "None stated".

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 381241-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Jan-2009	15-Feb-2009	37	24-Feb-2010	25-Feb-2010	WI		22-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	6050X	0	Left arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anaemia, Arthralgia, Dysmenorrhoea, Dyspnoea, Juvenile arthritis, Musculoskeletal stiffness, Myalgia, Rheumatoid arthritis, Swelling

Symptom Text: Started having joint pains that have steady and progressively gotten worse. She is now currently being seen by a Rheumatologist at Hospital and being treated for Rheumatoid arthritis symptoms, although she is not actually diagnosed with the disease as yet. ```3/1, 3/2, 3/4 & 3/5/10: Outpatient records received for dates of service 1/26/09 to 2/24/10 Dx: Arthralgia, Myalgia, Dysmenorrhea, Polyarticular arthritis. Began to develop joint pain and stiffness initially at knees, pain then spread to shoulders, subsequently developed pain of all joints of the body with significant swelling. Noted to be anemic but not fatigued. Pain reported to be very severe. Also reports intermittent trouble breathing, SOB, has had questionnable panic attacks in the past. 1+ swelling of IP's of thumbs. Walks with a flexed position and antalgic gait. Occupational and physical therapy recommended.

Other Meds:

Lab Data: ```3/1, 3/2, 3/4 & 3/5/10: Outpatient records received for dates of service 1/26/09 to 2/24/10 Labs and diagnostics: Iron 30 (L), creatinine 0.57 (L), Tot. Protein 8.1 (H), AST 14 (L), ESR 44 (H), Hemoglobin 8.8 (L), Hct. 28.3 (L), MCV 6

History: ```3/1, 3/2, 3/4 & 3/5/10: Outpatient records received for dates of service 1/26/09 to 2/24/10. PMH: Anemia, scoliosis.

Prex Illness:

Prex Vax Illns:

Vaers Id: **381242-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	24-Feb-2010	24-Feb-2010	0	25-Feb-2010	25-Feb-2010	ND		25-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling, Hypersensitivity, Lip blister, Pruritus, Urticaria

Symptom Text: Allergic reaction: Body hives, most severly on the face. Left eye swelling. Top lip itching and blistered. OTC allergy medication taken at approximately 10:00 PM same day.

Other Meds: 75 mcg Levothroid, 70 mg Vyvanse, 28 day Lo Ovral, 2,000 IU Vitamin D daily

Lab Data:

History: hypothyroid, allergic to penicillin, amoxicillin, and c-clor

Prex Illness: no

Prex Vax Illns:

Vaers Id: 381277-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	16-Oct-2008	16-Oct-2008	0	25-Feb-2010	26-Feb-2010	--	WAES0901USA03275	26-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Drug exposure during pregnancy, Hypertension, Induced labour, Pre-eclampsia

Symptom Text: Information has been received from a nurse practitioner for the Pregnancy Registry for GARDASIL concerning a 19 year old female patient with hypertension, asthma and obesity, no drug reactions/allergies, who on 23-JUL-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included lisinopril (manufacturer unknown) and montelukast sodium. On 16-OCT-2008, the patient was vaccinated with the second dose of GARDASIL (Lot # 660620/0571X) and was pregnant. The patient was due for the third dose on 21-JAN-2009 but did not receive it due to her pregnancy. The patient had a prenatal panel (normal). The patient came in for an OB visit. Her LMP was on 30-SEP-2008 and her EDD was 07-JUL-2009. Follow-up information was received from a staff person at nurse practitioner's office. It was reported that the patient was induced secondary to developing hypertension, and she had a vaginal birth on 24-JUN-2009 at term. The patient was seen in the office on 02-JUL-2009 for evaluation of her blood pressure and was treated with medication (unspecified) for hypertension by one of the physicians at that visit. The patient returned for further evaluation on 07-JUL-2009 and it was noted in the chart that both the mother and her baby were both doing well. The patient was last seen on 10-AUG-2009 by another physician in the practice for her postpartum visit and there was no indication of any problems for mother or baby. Follow up information has been received from the nurse practitioner that reported that the 19 year old female patient with chronic hypertension and with superimposed pre-eclampsia in her pregnancy was induced. On 24-JUN-2009, the patient was admitted to the hospital and was induced; the patient had a vaginal delivery of a healthy baby. There were no adverse events for the baby. On 28-JUN-2009 the patient and her baby were discharged to home. It was noted that on 09-JUL-2010 chart note, the baby was nursing well and that the baby was doing well. The nurse practitioner stated that "everything looked fine". Addi

Other Meds: lisinopril; SINGULAIR

Lab Data: diagnostic laboratory, several labs-prenatal panel (normal)

History:

Prex Illness: Pregnancy NOS (LMP = 9/30/2008); Hypertension; Asthma; Obesity

Prex Vax Illns:

Vaers Id: 381278-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Dec-2009	03-Feb-2010	43	25-Feb-2010	26-Feb-2010	FR	WAES1002USA03132	26-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depressed level of consciousness, Disturbance in attention, Dyspnoea, Headache, Malaise, Nausea, Nuchal rigidity, Pain, Serology test, Staring, Tremor, Vertigo

Symptom Text: Information has been received from a physician's wife concerning her 16 year old daughter with no relevant medical history, who received the first dose of GARDASIL (Lot# and Batch# not reported) on 22-DEC-2009. On 03-FEB-2010, she experienced malaise with nausea, vertigo, breathing difficulties; she was conscious but with an absent look, feebly responding. She also had tremor, headache but no fever. She was seen at the emergency care unit on 03-FEB-2010: examination was unremarkable, CT scan was normal. Since 03-FEB-2010, the patient experienced another 9 episodes of malaise with nuchal stiffness and pain, tremor, increased headache, and loss of vigilance. Such episodes were increasingly frequent. On 05-FEB-2010, MRI was normal. Lumbar puncture performed "on Monday" (i.e. 08-FEB-2010 or 15-FEB-2010) was unremarkable. Serology test were awaited. Headaches were described as continuous even between episodes of malaise, and did not regress on paracetamol or BI-PROFENID. On 15-FEB-2010, the patient was seen by a neurologist who did not know the diagnosis nor the cause of the patient's disorder. When asked by the patient's parents, the neurologist did not know whether the events were linked to vaccination with GARDASIL but could not rule it out either. At the time of reporting, the patient had not recovered. Other business partner numbers included E2010-01027. No further information is available.

Other Meds: Unknown

Lab Data: spinal tap, ??Feb10, lumbar puncture was unremarkable; computed axial tomography, 03Feb10, CT scan was normal; physical examination, 03Feb10, pt. seen at emergency care unit: examination unremarkable; magnetic resonance imaging, 05Feb10, MR

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **381279-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Feb-2010	12-Feb-2010	1	25-Feb-2010	26-Feb-2010	FR	WAES1002USA03435	26-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0465U	0	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Hypertonia, Incontinence, Loss of consciousness, No reaction on previous exposure to drug, Trismus

Symptom Text: Information has been received from a Health Authority (case n. 111894) through (local case n. IT076/10), concerning a 13 year old female with a remote medical history positive for palatoschisis corrected surgically at the age of 8 months and with recurrent otitis, who on 11-FEB-2010 at 11:00 am, was vaccinated with the first dose of GARDASIL (batch # NG17850, lot # 0465U). On 12-FEB-2010, about 36 hours post-vaccination, she presented with a critical episode during sleep with loss of consciousness, sphincteric discharge, hypertonus and trismus that lasted about 10 minutes. The outcome is recovered. The patient did not present with adverse events after previous vaccinations. The case is closed. Loss of consciousness, incontinence, hypertonus and trismus were considered to be immediately life-threatening. Lot check has been initiated. Other business partner numbers include E2010-01023. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Palatoschisis

Prex Illness: Otitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381312-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	25-Feb-2010	25-Feb-2010	0	25-Feb-2010	25-Feb-2010	PA		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	VF500CA		Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB349AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1099Y		Unknown	Unknown	
	MEN	SANOFI PASTEUR	V2907BA		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pallor, Presyncope, Tachycardia

Symptom Text: Severe nausea and patient became pre-syncopal with significant pallor and tachycardia.

Other Meds:

Lab Data: NOne

History: None

Prex Illness: NO

Prex Vax Illns:

Vaers Id: 381328-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jul-2007	16-Jul-2007	0	25-Feb-2010	25-Feb-2010	NC		22-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0243U		Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB163AB		Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Acute lymphocytic leukaemia, Blood iron increased, Diarrhoea, Herpes zoster, Hydrocephalus, Hyperbilirubinaemia, Hypertension, Memory impairment, Musculoskeletal pain, Nausea, Neuropathy peripheral, Neutropenia, Oedema peripheral, Pain in extremity, Pleural effusion, Spina bifida, Vomiting

Symptom Text: Pain in L arm and shoulder, lasted to the end of the month. Diagnose with acute lymphoblastic leukemia. Some of T-cells had problem and hospitalization was required. ```3/9, 3/11 & 3/12/10 Discharge summary and hospital records received for dates of service 7/24/07 to 8/26/09 Dx: Lymphocytic leukemia, hyperbilirubinemia with iron overload, neutropenia, Mucolitis, resolved, pleural effusion, shingles, hypertension, peripheral neuropathy, peripheral edema, Spina Bifida Unspecified region with Hydrocephalus-Arnold-Chiari Malformation. Presented with back and shoulder pain, atypical lymphocytes suggestive of blasts. Lymphocytic leukemia originally diagnosed in July 2007. Treated with IV Vincristine, 6MP and methotrexate which resulted it persistent nausea and vomiting. Methotrexate d/c'd and n&v abated. Transfused with blood and platelets. LP done with elevated protein. Porta-cath placed. Experienced some short term memory loss. Acute intermittent abdominal pain and diarrhea. Started on oral chemotherapy.

Other Meds: none

Lab Data: bone marrow report; biopsy; CBC; CT chest, abdomen pelvic w/contrast; aspirate smears; core biopsy; clot section. ```3/9, 3/11 & 3/12/10 Discharge summary and hospital records received for dates of service 7/24/07 to 8/26/09. Labs and

History: hydrocephalus. ```3/9, 3/11 & 3/12/10 Discharge summary and hospital records received for dates of service 7/24/07 to 8/26/09. PMH: Congenital hydrocephalus with VP shunt placement, high risk preemie, pulmonary effusion with collapse of lung and pneumonia. Allergies to PCN, platelets hives, septra.

Prex Illness: do not remember

Prex Vax Illns:

Vaers Id: **381355-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Feb-2010	23-Feb-2010	0	26-Feb-2010	26-Feb-2010	MI		26-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500830P	0	Unknown	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049AA	5	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	1075Y	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	819Y	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U3045AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Body temperature increased, Dizziness, Fatigue, Headache, Injection site erythema, Injection site swelling, Malaise, Pyrexia

Symptom Text: Later in evening, experienced headache, dizziness, temp 100 degrees F. Next day 2/24/10 - fever of 102 degrees F. . Varicella site red and swollen. Fatigue - slept 20 hrs. Malaise and stomach cramps. Fever resolved on 2/26/10.

Other Meds: None

Lab Data:

History: Allergy to bees.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381357-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	17-Feb-2010	17-Feb-2010	0	25-Feb-2010	26-Feb-2010	NC		26-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Dizziness, Erythema, Headache, Pain, Pain in extremity, Rash maculo-papular, X-ray normal

Symptom Text: 2/25/10 Pt was seen 2/20/10 seen pv. Received immun 2/17/10 in R arm. She c/o R arm pain that evening and next day. Seen by another MD 2/19, did x-rays, nothing found. She describes the pain as burning, esp face. Then also c/o legs hurting and face burning. She also c/o HA and dizziness. No fainting, no cough or URI, no vomiting or diarrhea, appetite normal, T max 100.2. No physical changes noted on exam except winces with pain on palpation and movement of R arm and legs but from pressure. No skin findings except 3 or 4 <1cm maculopapules, pink on L iliac crest area, no bulla, no pus, no wheals. No redness or swelling of R arm or legs. No swelling of face. Cheeks sl. pink. This was temporally related to the immunization.

Other Meds:

Lab Data:

History: Amox caused rash 7/05

Prex Illness:

Prex Vax Illns:

Vaers Id: **381359-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Sep-2009	22-Sep-2009	0	26-Feb-2010	26-Feb-2010	FL		26-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	MSD0671Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: the customer stated she had no monthly period for three months after HPV#2 dose rececived on 09/22/2009.

Other Meds:

Lab Data: none.

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **381428-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
39.0	F	09-Sep-2009	25-Sep-2009	16	26-Feb-2010	01-Mar-2010	FR	WAES1002USA03282	01-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	K5427		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Dermatomyositis, Inappropriate schedule of drug administration

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail concerning a 39 year old female who on 09-SEP-2009 was vaccinated with a dose of GARDASIL vaccine intramuscularly. Concomitant therapy included norethindrone and VENTOLIN. On 25-SEP-2009 the patient experienced dermatomyositis and was hospitalized. Lab data: CK 1657 after one week high dose steroid; on 16-OCT-2009, neutrophilia, eosinophilia just over upper Limit of Normal (wbc11.5), rheumatoid factor 1050iu/ml (n0-14); anti nuclear antibody, homogeneous pattern 1:160; erythrocyte sedimentation rate 20mm. Other lab investigations included high CK 2000, rheumatoid factor 1000 and pos "anf". The patient was treated with prednisone. The outcome was unknown. The reporter felt that dermatomyositis was possibly related to therapy with GARDASIL vaccine. Dermatomyositis was considered to be disabling. The original reporting source was not provided. Additional information is not expected.

Other Meds: VENTOLIN; norethindrone

Lab Data: Diagnostic laboratory test, anti nuclear antibody, homogeneous pattern 1:160; WBC count, 16Oct09, 11.5; eosinophil count, 16Oct09, just over Upper Limit of Normal; neutrophil count, 16Oct09, just over Upper Limit of Normal; serum creatine k

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **381429-1** **Related reports:** 381429-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Feb-2010	25-Feb-2010	0	26-Feb-2010	26-Feb-2010	TN		24-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	662629/1317	0	Right leg	Unknown	
TDAP	SANOFI PASTEUR	C3352AA		Left leg	Intramuscular	
MNQ	SANOFI PASTEUR	43080AA	0	Left leg	Intramuscular	
HEPA	MERCK & CO. INC.	666201/1538Y	0	Right leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Drug hypersensitivity, Dysstasia, Ear pain, Hypersensitivity, Nausea, Ocular hyperaemia, Palmar erythema, Pruritus, Urticaria

Symptom Text: ears started hurting, eyes bloodshot, weakness,dizziness,nausea, unable to get up without help. Call Dr. then 911 and went by ambulance to ER. They gave her meds to counter allergic reation. Observed for several hours at ER and was sent home, with prescription for Epi Pen and Zyrtec, Benedryl. ```ED records, ED patient discharge summary, received 3/23/10. Service date 2/25/10. Assessment: Allergic reaction - Drug. Patient developed hives all over, itchy skin, nausea, dizziness. Since arrival at ED symptoms have improved and hives are gone. Slight itching in hands. Redness palms. Patient feels better and is discharged to home.

Other Meds: adderall

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **381429-2** **Related reports:** 381429-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Feb-2010	25-Feb-2010	0	16-Mar-2010	17-Mar-2010	TN	WAES1003USA00893	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1538Y		Right leg	Unknown	
	HPV4	MERCK & CO. INC.	1317Y	0	Left leg	Intramuscular	
	TDAP	SANOFI PASTEUR	C3352AA		Right leg	Unknown	
	MNQ	SANOFI PASTEUR	43080AA		Left leg	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Paraesthesia, Urticaria

Symptom Text: Information has been received from a physician and a licensed practical nurse concerning a 14 year old female patient with attention deficit disorder and allergic to penicillin who on 25-FEB-2009 was IM vaccinated with a first dose of GARDASIL (lot no. 662529/1317Y) given in left upper thigh; a dose of VAQTA (lot no 666201/1538Y) given in right upper thigh; a dose of MENACTRA (lot # 430800AA) given in left lower thigh and a dose of ADACEL (lot # C3352AA) given in right lower thigh. Concomitant medication included ADDERALL. It was reported that the patient called the physician's office at the afternoon, the patient experienced hives, nausea and dizziness and also complained of tingling in both legs. Patient had taken 12.5 mg of BENADRYL twice before going to the emergency room. The patient was seen at approximately 23:00 PM the same day and symptoms were gone. Patient received a dose of SOLU MEDROL IV and ZANTAC prior to being discharged from emergency room. At the time of report the patient was recovered. Upon internal review, hives, nausea, dizziness and tingling in both legs were considered to be other important medical events. No further information is available.

Other Meds: ADDERALL tablets

Lab Data: unknown

History:

Prex Illness: Attention deficit disorder; Penicillin allergy

Prex Vax Illns:

Vaers Id: **381430-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Oct-2009	12-Oct-2009	0	26-Feb-2010	01-Mar-2010	FR	WAES1002USA03345	01-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	1422U		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NJ29430		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Anaphylactic reaction, Chest discomfort, Cold sweat, Erythema, Pallor, Paraesthesia, Rash, Rash macular

Symptom Text: Information was obtained on request by the company from the agency via a public case details form concerning a 12 year old female patient who on 12-OCT-2009 at 10:20 am was vaccinated with a dose of GARDASIL (Lot#NJ29430, batch #NK20450) and also was vaccinated with a dose of RECOMBIVAX HB, (Lot#1422U, batch# NJ11300). On 12-OCT-2009, at 10:35 the patient developed a rash to chest (blotchy and raised edges) and a red rashy face. The patient also complained of heavy chest. Then at 10:40 am, the patient experienced sore abdomen, pins and needles to hands, heavy chest, rash to chest subsiding, pale skin and hands clammy. It was noted that the patient did not have respiratory problems and that the patient was alert. An ambulance was called and the patient was treated with ADRENALINE. This event required that the patient was treated in the accident emergency department and caused or prolonged inpatient hospitalization (dates not reported). At a subsequent clinic visit this ADR was upgraded to anaphylaxis. At the time of the reporting, the outcome of the patient was unknown. The agency considered that hypersensitivity, rash and anaphylactic reaction were possibly related to therapy with GARDASIL and RECOMBIVAX HB. The original source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381431-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Feb-2010	23-Feb-2010	1	26-Feb-2010	26-Feb-2010	WA		26-Feb-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1538Y	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3048AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Myalgia, Oropharyngeal pain, Rash

Symptom Text: Facial rash, sore throat, body aches - T - 91'. (Allergic reaction)

Other Meds: Albuterol PRN

Lab Data: None

History: No - Parent reports similar reaction to orchard sprays.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381472-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Jan-2010	29-Jan-2010	0	26-Feb-2010	01-Mar-2010	SC		01-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1070Y	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	UF499BA	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3058AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1013Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Pallor, Unresponsive to stimuli

Symptom Text: pt given 4 vaccine shots on 1/29/2010, after last vaccine hpv pt. became very pale unresponsive with petit mild seizure, applied cold compresses to face neck and forehead , at which time pt responded , was alert and was given sips of ginger ale, then she was allowed to lie down on exam table for 20-30 minutes ,was later discharge home with father.

Other Meds: none

Lab Data: none

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **381518-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Jan-2010	14-Jan-2010	0	01-Mar-2010	01-Mar-2010	MA		21-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U3351AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP103AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Muscle rigidity, Nausea, Syncope

Symptom Text: Pt received vaccines in supine position. Pt received TIV in L arm. Pt received HPV in R arm c/o nausea, CMA placed a cold pack on pt's neck and took sip of H2O and asked RN to come into room. Held off giving H1N1 for 5-10 minutes, at pt's insistence gave H1N1 and within seconds pt developed syncope became rigid then jerking of arms and legs with paused breathing for 15 sec. Pt responded quickly alert and oriented.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **381521-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	F	02-Mar-2009	11-Nov-2009	254	01-Mar-2010	02-Mar-2010	--	WAES0905USA03368B1	02-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Congenital naevus, Constipation, Diarrhoea, Drug exposure during pregnancy, Faeces discoloured, Haemangioma, Jaundice neonatal, Pyrexia, Rash macular, Rhinitis, Rhinorrhoea, Skin hyperpigmentation, Upper respiratory tract congestion

Symptom Text: Information has been received from a physician via medical records concerning an 8 day old female patient with no known drug allergies, who was born to a 22 year old female patient with left ovarian cyst history and no drug reactions or allergies who in September 2008, was vaccinated with a first dose GARDASIL (lot # not reported). On 02-MAR-2009 she received the third dose of GARDASIL (lot # not reported). After she received three doses of vaccine she was found out that she was pregnant. Patient had last menstrual period on 13-FEB-2009. It was reported that the mother had a normal pregnancy. On 11-NOV-2009, with no complication during labor/delivery at 38 weeks from last menstrual period she had a normal female baby which was born via vaginal delivery. The baby was slightly yellow in the hospital, but all values were within normal limits. The baby weight was 6 lb and 0 ounce, length 19 inches and apgar score 9/9. On 19-NOV-2009, the 8 day old patient presented to the physician's office for an outpatient's visit with congestion and a yellow drainage from her nose that began 3 days ago, on 16-NOV-2009. Review of systems were normal except that the patient was positive for jaundice in her face to her chest, that it seems to was improving by her mother. During the nasal septum/mucosa test was found that was partially obscured by purulent drainage. The patient had normal respiratory rate and pattern with no distress, normal breath sounds with no rales, rhonchi, wheezes or rubs. On the same day a Flu test and a RSV were performed and the results were negative. The physician's assessment was nasal congestion. The physician's order's included: Radiology/test: Non invasive ear or pulse oximetry for oxygen saturation; single determination; A RSV antigen EIA and influenza A or B: antigen detection by enzyme immunoassay (X2). No prescriptions were generated, provider does have access to a qualified e-prescribing system. The physician's recommendations included: humidifier/vaporizer, bulb suction and nasal saline, and monito

Other Meds:

Lab Data: Serum influenza A virus, 11/19/09, negative; nasal aspirate RSV, 11/19/09, negative; Apgar score, 11/11/09, 9/9; serum influenza B virus, 11/19/09, negative

History: Ovarian cyst

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381522-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Jan-2010	15-Jan-2010	2	01-Mar-2010	02-Mar-2010	FR	WAES1002USA03409	02-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NK4587	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dizziness, Headache, Muscle contractions involuntary, Muscle spasms, Muscle twitching, Palpitations, Pyrexia

Symptom Text: Information has been received by the health authority (HA ref. NO-NOMAADVRE-FHI-2010-9949/FHI 10-4501). It was reported that a 12 year old girl was vaccinated with the second dose of GARDASIL batch # "NK4587" (one figure missing), parenteral route 0.5 ml) on 13-JAN-2010. The health authority coded dizziness, fever, pain stomach, cramps legs and headache (causalities possible) with onset on 15-JAN-2010 and fasciculation (causality possible) with onset in January 2010. (HA stated 16-JAN-2010 or 26-JAN-2010. Two separate reports, different information (from family doctor and policlinics). The duration of fever an stomach pain was four days, while the dizziness, leg cramps and headache lasted for an unspecified number of days. The fasciculation's, located to legs, thighs and upper extremities, were still not recovered at time of reporting. Tests performed on 08-FEB-2010: pulse rate 77, blood pressure 117/67, arterial blood oxygen saturation test 100%, and neurological examination (no special findings). The reporter summarized the test results: several examinations were carried out policlinical. The only finding was small twitches in both lower extremities, by palpitations and tonus examinations. At the time there was no fasciculation's. No more information on the tests was provided in the report. According to the report the girl was referred to magnetic resonance (MR) caput and EEG and was to be followed up at the policlinic. FHI has asked for further information from the policlinic. The outcome is recovered for all but the fasciculation that was still not recovered as to be the lower extremities on 08-FEB-2010. This case was closed. The reporter felt that the events were considered to be Other Important Medical Events. Other business partner number included: E2010-01059. No further information is available.

Other Meds: Unknown

Lab Data: Pulse oximetry, 08Feb10, 77; Blood pressure measurement, 08Feb10, 117/67; Neurological examination, 08Feb10, No special findings; Arterial blood O2 saturation, 08Feb10, 100%

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 381523-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Oct-2009	08-Oct-2009	1	01-Mar-2010	02-Mar-2010	FR	WAES1002USA03649	02-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1693U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT General physical health deterioration, General symptom, Infection, Pyrexia, Sepsis

Symptom Text: Case received from a Health Authority on 17-FEB-2010 under reference # 2010-04050. A 15 (also reported as 16) years old female patient received on 07-OCT-2009 the first dose of GARDASIL (batch # NH55610, lot #1693U, site of administration not reported) via intramuscular route. On 08-OCT-2009, one day post vaccination, the patient developed fever and exhibited signs of sepsis. The patient was hospitalized on 08-OCT-2009 in a reduced general condition. Her body temperature at admission was 38 C after taking paracetamol (dose not known). Blind treatment with CO-AMOXI-MEPHA was started for an unclear focus of infection. On 08-OCT-2009, C-reactive protein (CRP) result 132. On 09-OCT-2009, CRP result 150. The patient was discharged on 10-OCT-2009. At the time of the report, the patient was being treated by her general practitioner for diffuse general symptoms that were not described more closely. The health authority assessed the causal relationship to the vaccine as possible. No further information was available. Other business partner numbers include E2010-01072.

Other Meds: Unknown

Lab Data: Body temp, 08Oct09, 38 C; serum C-reactive protein, 08Oct09, 132 mg/l; serum C-reactive protein, 09Oct09, 150 mg/l

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381558-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Feb-2010	22-Feb-2010	0	01-Mar-2010	01-Mar-2010	TX		01-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dyspnoea, Headache, Pain, Pyrexia, Rash

Symptom Text: 101 fever, stomach ache, headache, hurting all over. Since had rash that appears in evenings, shortness of breath, constant headache and stomache ache.

Other Meds: Loestrin

Lab Data: blood work so far.

History: PCOS

Prex Illness: no

Prex Vax Illns: sick several times~HPV (Gardasil)~1~14.67~Patient

VAERS Line List Report

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381559-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Mar-2010	01-Mar-2010	0	01-Mar-2010	01-Mar-2010	FL		01-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	2	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1005Y	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3044AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Presyncope

Symptom Text: lightheadedness, pre-syncopal episode - resolved after lying flat and resting for 10 minutes occurred after HPV vaccine

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 381576-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Jan-2010	13-Jan-2010	2	01-Mar-2010	02-Mar-2010	KS		02-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C3250AA	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1353Y	2	Left arm	Intramuscular	
HEP	MERCK & CO. INC.	1251Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Anaemia, Appendicectomy, Chest pain, Cyanosis, Dizziness, Dyspnoea, Fatigue, Heart rate decreased, Hypotension, Intensive care, Intestinal obstruction, Nausea, Oxygen saturation decreased, Ultrasound scan abnormal

Symptom Text: Parent states child c/o fatigue, nausea, abd. pain, short of breath, chest pain, dizziness. Was seen by doctor 3 days later: Liver enzymes, anemic. Sonogram discovered blocked intestine. Mas Citrate with some relief. 01/22/2010 c/o severe chest pain and blue at lips. Dr. provided breathing treatment and O2 sats began to bottom out. Facility placed pt in ICU at that time. Sent out via ambulance to another hospital. In hospital for 3 days. Only time these s/s occured was when pt was in upright position. Pt sent home with Holter Monitor. Holter monitor results was normal during event of not getting enough air. Pt had echo Cardiogram was normal. Had low B/P with slow pulse. As of 3/1/2010 child suffers from abd pain, occ sob. Had surgery for appendix out.

Other Meds:

Lab Data: Holter Monitor, echo cardiogram, Liver panel, CBC

History: None

Prex Illness: None. No illness

Prex Vax Illns:

Vaers Id: **381594-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		02-Mar-2010	03-Mar-2010	--	WAES1002USA03213	03-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician via observant LLC concerning a 21 year old female who was vaccinated with GARDASIL. There was no concomitant medication. In summer 2009 the patient passed out after GARDASIL shot. The patient recovered with sequelae from passed out. The reporter considered passed out to be an other important medical event. No further information is available.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **381595-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Feb-2010	20-Feb-2010	0	02-Mar-2010	03-Mar-2010	FR	WAES1002USA03561	03-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353X	1	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Apnoea, Back pain, Dizziness, Fall, Head injury, Immediate post-injection reaction, Muscle rigidity, Nausea, Presyncope, Trismus

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 13-OCT-2008 was vaccinated with first dose of GARDASIL. On 20-FEB-2010, the patient was vaccinated with a dose of GARDASIL (dose and route not reported, lot number 1353X, batch number NL24560). There was no concomitant medication. On 20-FEB-2010, immediately after vaccination, the patient experienced vaso-vagal. It was noted that the patient felt light headedness, nausea and giddiness. She lied down for 2 minutes and after getting up, she felt dizzy and fell down. Her body became contorted and she fell down banging her head. The patient had lock jaw and for some time her breathing stopped. She was given painful stimuli and she regained consciousness after two minutes. Her breathing was normal. She complained of severe backache. No prescription drug treatment was given for this event. Dizziness/lightheadedness, vaso-vagal, lock jaw, body rigidity, stop breathing for a while, fell down banging her head, complained of severe backache and nausea were considered to be immediately life-threatening. A lot check has been initiated. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 381596-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		02-Mar-2010	03-Mar-2010	TX	WAES1002USA03851	03-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diagnostic procedure, Laboratory test, Muscular weakness, Myalgia, Pain in extremity, Syncope

Symptom Text: Information has been received from a office manager concerning a 13 year old female patient with no known drug reactions or allergies and no pertinent medical history noted who on an unspecified date, was intramuscularly vaccinated with the third dose of GARDASIL. There were no known concomitant medications. The office manager reported that approximately one year after she completed the GARDASIL series the patient complained of generalized muscle weakness, muscle and leg pain and syncope. It was reported that various lab and diagnostic studies were performed. The patient was seen by a cardiologist but the office manager did not know the exact labs and studies performed. The patient sought medical attention by visiting the doctor's office. The office manager stated that the patient was still being followed up by different physicians. At the time of the report, the office manager did not know whether the patient's symptoms had resolved. Generalized muscle weakness, muscle and leg pain and syncope were considered to be other important medical events by the office manager. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **381597-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	26-Jun-2008	14-Sep-2008	80	02-Mar-2010	03-Mar-2010	--	WAES0810USA02447B1	03-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervix disorder, Drug exposure during pregnancy, Foetal disorder, Ultrasound scan abnormal

Symptom Text: Information has been received from an office manager concerning an infant whose 21 year old mother with a history of pyloric stenosis, papanicolaou smear abnormal, ovarian cysts, prior loop electrosurgical excision procedure, pre-term delivery (35 weeks) with pre-eclampsia and pre-term premature rupture of membranes with her prior pregnancy who on 26-JUN-2008 and 29-SEP-2008 was vaccinated intramuscularly in the right deltoid with a first and second 0.5 ml doses, respectively, of GARDASIL (Lot # of the second dose: 0573X). There was no birth defect in previous pregnancy. There was no concomitant medication. Subsequently the patient became pregnant. The patient was seen at the practice. On 14-OCT-2008, the patient was 5-6 weeks gestation. Estimated date of delivery was approximately 09-JUN-2009. On 20-OCT-2008 an ultrasound revealed that the fetal heart rate was 124 bpm and the cervix was 3 cm. The office manager reported that they did not have any information on the infant, and she did not call the patient concerning this registry. There was a note written at postpartum visit that the infant was seeing a cardiologist for heart valve. Heart valve disease was considered to be congenital anomaly. The mother's experience is reported in WAES #0810USA02447. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Pyloric stenosis; Papanicolaou smear abnormal; Ovarian cyst; Premature rupture of membranes; Pre-eclampsia; Early onset of delivery; Loop electrosurgical excision procedure

Prex Illness:

Prex Vax Illns:

Vaers Id: **381598-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-May-2009	18-May-2009	0	02-Mar-2010	03-Mar-2010	OH	WAES0905USA02546	03-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy Registry product, concerning a 15 year old female with no medical history or allergies who on 18-MAY-2009 was vaccinated intramuscularly with the first and only dose of GARDASIL while pregnant (LMP=end of April 2009, EDD=04-Feb-2010). Concomitant therapy included LUPRON, ROCEPHIN, azithromycin and FLAGYL. No adverse effect reported. Laboratory tests included positive pregnancy test. Medical attention was sought. Follow-up information was received from the physician for GARDASIL, a Pregnancy Registry product, concerning the 15 year old female with post-traumatic stress disorder and conversion disorder. Concomitant therapy included LUPRON, from 18-MAY-2009, 11.25 mg, "93mis" for the menstrual supplement, ROCEPHIN, from 18-MAY-2009, 125 mg, "XT", for "SII tx/presumptive tx", azithromycin, from 18-MAY-2009, 1 gm, "XT", for "SII tx/presumptive tx", and FLAGYL, from 18-MAY-2009, 2 gm, "XT", for the treatment of trichomonas. Estimated conception date is 02-MAY-2009. The patient underwent elective termination on an unknown date within 6 weeks from LMP. Upon internal review, the patient's elective termination was considered to be an other important medical event. Additional information is not available.

Other Meds: azithromycin; ROCEPHIN; LUPRON; FLAGYL

Lab Data: Beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 4/30/2009); Post-traumatic stress disorder; Conversion disorder; Routine health maintenance; Trichomonas on

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381599-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	26-May-2009	Unknown		02-Mar-2010	03-Mar-2010	FR	WAES1002USA03320	03-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Asthenia, Dizziness, Headache, Nausea, Pain, Palpitations, Sensory loss, Thirst, Vision blurred, Weight bearing difficulty

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail concerning a female who on 26-MAY-2009 was vaccinated intramuscularly 1 dose, 1 time with GARDASIL. On an unspecified date, the patient experienced weight bearing difficulty, anxiety, asthenia, dizziness, headache, nausea, thirst and vision blurred and was hospitalized. The patient was unable to weightbear/needing assistance for 1/52. The patient also had weakness, body aches, headaches, nausea, anxiety, decreased sensation in legs, increased thirst, dizzy, blurred vision and palpitations. All the events required a visit to the doctor. At this time, the patient did not recover from the events. The reporter felt that weight bearing difficulty, anxiety, asthenia, dizziness, headache, nausea, thirst and vision blurred were possibly related to therapy with GARDASIL. The original reporting source was not provided.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381605-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Aug-2009	18-Aug-2009	1	02-Mar-2010	02-Mar-2010	CT		25-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	AC52B033BA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3011AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain

Symptom Text: Severe abd pain the next day after receiving the first two doses of GARDASIL on 8-17-09 and 10-21-09. Not reported to us after 1st dose or 2nd dose.

Other Meds: None known

Lab Data: None

History: Allergy to PCN; sour apple candy and chocolate pop tarts (hives)

Prex Illness: None

Prex Vax Illns: Rash~DTaP (no brand name)~3~0.50~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381624-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Mar-2010	01-Mar-2010	0	02-Mar-2010	02-Mar-2010	CA		29-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2875AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1236Y	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0819Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Hyperhidrosis, Immediate post-injection reaction, Loss of consciousness, Pain in extremity, Pallor

Symptom Text: Child was given HPV #2 at 8:15 AM in the left deltoid. Then Varicella was given in the left SQ. We then moved to the right arm where the MCV4 was given in the right deltoid. Immediately after MCV4 was given, child closed her eyes and complained of pain to the right arm and then fell to the side, passing out. She was pale and sweaty and came to in about 1 minute. She was awake and alert and responsive stating "cool, I have never passed out before". We had her lay down for 20 minutes with her feet elevated and gave her hard candy and water to drink. She did not have breakfast before coming to the clinic.

Other Meds:

Lab Data:

History: None

Prex Illness: She had mild cold symptoms but temp. was 98.8

Prex Vax Illns:

Vaers Id: **381644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Feb-2010	22-Feb-2010	0	02-Mar-2010	02-Mar-2010	VA		02-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Fatigue, Pyrexia

Symptom Text: Onset fever day of vaccine, max temp (103.5 x 4 d), stomach pain, fatigue since shot given.

Other Meds: Griseofulvin

Lab Data:

History: Bells Palsy; Lyme's disease

Prex Illness: None identified

Prex Vax Illns:

Vaers Id: 381722-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Mar-2008	06-Mar-2008	0	03-Mar-2010	04-Mar-2010	FR	WAES1002USA01723	04-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Arthralgia, Back pain, Balance disorder, Dizziness, Headache, Joint swelling, Malaise, Migraine, Musculoskeletal chest pain, Neck pain, Pain in extremity, Paraesthesia, Peripheral coldness, Similar reaction on previous exposure to drug, Wheelchair user

Symptom Text: Information was obtained on request by the company from the agency via a public case details form concerning a 12 year old female who on 06-MAR-2008 was vaccinated with first dose of GARDASIL (lot # not reported). On an unspecified date she received second dose (lot # not reported). On 11-SEP-2008 she received third dose of GARDASIL (lot # not reported). On 06-MAR-2008 after first injection she started feeling unwell with a minor headaches. After second injection she experienced severe headaches consistent, progressing to severe intense migraines, neck and back pain, pins and needles in hands, face and dizzy spells and loss of balance. After third injection she experienced leg and back pain (wheelchair was needed as unable to walk unaided), migraine, back, leg and neck worse and rid pain. Four days after last injection she experienced foot pain sore ankle with swelling, pins and needles, foot cold and unable to walk properly. The patient was treated with PANADEINE FORTE, diazepam, MOBIC, physiotherapy, endeplo and NAPROSYN SR 750. At the time on the report the patient had not recovered from headache, abasia, balance disorder, dizziness, migraine and paraesthesia. The agency considered that headache, abasia, balance disorder, dizziness, migraine and paraesthesia were possible related to therapy with GARDASIL. The original reporting source was not provided. Follow up information has been received from agency who considered the events of leg pain and back pain (wheelchair was needed to walk unaided) to be incapacitating/disabling. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381723-1** **Related reports:** 381723-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Jun-2008	03-Jun-2008	0	03-Mar-2010	04-Mar-2010	VA	WAES1001USA00367	23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abscess, Acute sinusitis, Anxiety, Arthralgia, Cellulitis, Dysmenorrhoea, Oedema peripheral, Panic attack, Paronychia, Rheumatoid arthritis, Rheumatoid factor increased, Tendonitis, Upper respiratory tract infection, Viral pharyngitis

Symptom Text: Information has been received from a Licensed Practical Nurse (L.P.N) concerning a 19 year old female patient with no pertinent medical history and no known drug allergy/drug reactions who on 03-JUN-2008 was vaccinated with the first dose of GARDASIL (lot # 655604/0052X); on 04-AUG-2008, the patient received her second dose of GARDASIL (Lot # 0250X) and on 18-DEC-2008, the patient was vaccinated with her third dose of GARDASIL (Lot # 0947X). Concomitant therapy included hormonal contraceptives (unspecified), ZOLOFT and MOBIC. It was reported that the patient developed rheumatoid arthritis in the fingers of her right hand, feet and legs after vaccination with GARDASIL. The patient was diagnosed in June 2009. It was reported that the patient was seen in the office. A blood work was performed on an unspecified date (results not provided). At the time of the report the patient had not recovered. Follow up information was received from the Licensed Practical Nurse (L.P.N) who reported that the AE onset date was in June 2009; the rheumatoid arthritis was diagnosed through blood work (results not available). It was reported that there were no concomitant vaccines, only concomitant therapy which included birth control pills and ZOLOFT which was prescribed at the end of August 2009. It was also reported that the patient was first seen in another office in September 2009. It was reported that MOBIC was prescribed for the treatment of rheumatoid arthritis. The patient was referred to the rheumatologist. The patient was doing well on MOBIC, ZOLOFT and PLAQUENIL. Follow up information was received from the Licensed Practical Nurse (L.P.N) who reported that the patient a 19 year old female student, received the three doses of GARDASIL intramuscularly on 03-JUN-2008, at 11:20 am in left gluteus; on 04-AUG-2008, at 12:57 pm in right gluteus and on 18-DEC-2008, at 11:18 am in left gluteus. There were no illnesses at the time of vaccination. At the time of the report the patient had not recovered. The reporter considered rheumatoi

Other Meds: Hormonal contraceptives; ZOLOFT

Lab Data: Diagnostic laboratory, blood work; rheumatoid arthritis was diagnosed```3/5 and 3/8/10 Medical records received for dates of service 1/24/08 to 9/11/09. Labs and diagnostics: Rheumatoid factor positive.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 381724-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
-0.7	M	Unknown	11-Apr-2009		03-Mar-2010	04-Mar-2010	--	WAES0910USA00755B1	26-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Congenital anomaly, Drug exposure during pregnancy, Pneumothorax, Polydactyly, Premature baby, Renal cyst, Respiratory distress, Weight decrease neonatal

Symptom Text: Information has been received from a certified nurse midwife concerning a male patient who was exposed through his mother who on 22-APR-2008, was vaccinated with her first dose of GARDASIL vaccine (Lot#659441/1446U) a pregnancy registry product. On 22-JUL-2009 his mother was vaccinated with her second dose of GARDASIL vaccine (Lot#662404/0312Y), along with a hepatitis A vaccine (inactive) (manufacturer unknown). Concomitant therapy included vitamins (unspecified) and iron (unspecified). On 30-DEC-2009, at 35 weeks of gestation, the patient's mother experienced a preterm delivery. The baby was a normal male baby (weight 5 pounds 15 ounces, the head circumference was 33.5 cm, the length was 19 inches, the apgar score was 4/8). The baby did not presented congenital anomalies. It was reported that the baby also experienced cysts on kidneys and respiratory distress after delivery. The baby's outcome for cyst on kidneys and respiratory distress were unspecified. Additional information has been received from a physician via medical records concerning a male baby who on 30-DEC-2009 received the first dose of hepatitis B vaccine, recom (manufacturer unknown). The patient lives with his mother, who is 16 years old and her mother in a house with a small dog and kitten. His family history was remarkable for maternal cousin who died of SIDS at 10 weeks of age. No deafness before the age of five. No hip disorders. No kidney disorders. No bleeding disorders. No heart disease. On 31-DEC-2009, the patient's chest X-ray showed improving of the radiographic appearance of the chest. The persistent parenchymal density could indicate a degree of respiratory distress syndrome. On 01-JAN-2010, the patient's chest X-ray showed a continued improvement of the radiographic appearance of the chest with some persistent hazy opacity in both lungs, which may indicate a mild degree of respiratory distress syndrome. On 07-JAN-2010, the patient was taken to a physician for a newborn visit, the patient was seven days old and was born at 37weeks via

Other Meds: Iron (unspecified), mg; Vitamins (unspecified)

Lab Data: Chest X-ray, 12/31/09, improving radiographic appearance of the chest; Chest X-ray, 01/01/10, continued improvement of the radiographic appearance of the chest; Apgar score, 12/30/09, 4.8

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **381725-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.3	M	09-Feb-2009	09-Feb-2009	0	03-Mar-2010	04-Mar-2010	FL	WAES0903USA02327B1	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acarodermatitis, Dermatitis, Eczema, Hypospadias, Impetigo, Leukopenia, Purulence, Rash erythematous, Rash papular, Scab, Staphylococcal infection

Symptom Text: Information has been received from a physician via pediatric medical records concerning a male baby with no known drug allergies whose mother with scabies was vaccinated on approximately 17-Aug-2008 with a first dose of GARDASIL. The patient's mother received a 0.5 mL third dose of GARDASIL while she was pregnant. On 27-Oct-2009, the patient was born with a weight of weight 7 pounds and a length of 20 inches. On 29-Oct-2009, the patient was vaccinated with HEP B. On 02-Nov-2009, the patient was seen for evaluation. The patient was receiving enteral nutrition 4gQ4H. Physical examination was normal except for pharynx which had white plaques and of genitals which had a left hypospadias. It was noted that the patient's mother was not a smoker and the patient's father was in prison. The infant was prescribed nystatin suppository for the white plaques in the pharynx. On 23-Nov-2009, at 1 month of age, the patient was seen again. This time, the physical examination was normal except for genitals. Hypospadias was noted again. The infant's skin was reported as abnormal described as Staph dermatitis. The plan was to continue the nystatin and BACTROBAM ointment. On 01-Dec-2009, the patient was seen for his rash. It was noted that the skin had a red, crusted yellow raised area papules to back and red raise dry papules to face. During this appointment, the patient was diagnosed with dermatitis. The patient's impetigo / and staphylococcal dermatitis was still present and the infant was to continue the BACTROBAM. The patient was scheduled to return to the office one week later. On the visit of 08-Dec-2009, the patient's rash persisted. He was diagnosed with scratchy purulent crust on trunk and back. The patient was diagnosed with scabies. The patient was prescribed ELOMET. On 22-Dec-2009, the patient had another office visit. The physical examination was normal except for the genitals, skin and the abdomen (hiatal hernia was found). On this day the infant was vaccinated with his second dose of ENGERIX-B, PENTACEL and PREVNAR. O

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Scab

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381731-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Dec-2009	Unknown		03-Mar-2010	03-Mar-2010	NC		03-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Pt states had numbness in both hands for 2 weeks after last GARDASIL (#2) shot. Wanted to know when she can get #3 (last one).

Other Meds:

Lab Data:

History:

Prex Illness: None known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381766-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Feb-2010	15-Feb-2010	0	03-Mar-2010	04-Mar-2010	--		04-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: PATIENT RECIEVED VACCINE, WAS WALKING OUT OF BUILIDING AND FAINTED.

Other Meds:

Lab Data: NONE

History: NONE

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381780-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Feb-2010	24-Feb-2010	1	03-Mar-2010	04-Mar-2010	NJ		04-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Left arm	Unknown	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500850P	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Headache, Hypoaesthesia, Urticaria, Vomiting

Symptom Text: 24 hours after GARDASIL and live H1N1 given, pt developed hives on right arm. Within 20 minutes hives spread to the chest onto the back. 48 hours after inoculation pt started to experience numbness in finger tips, headaches, vomiting and diarrhea.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381801-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Feb-2010	23-Feb-2010	0	04-Mar-2010	04-Mar-2010	NY		29-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Rash macular, Urticaria

Symptom Text: Hives, coughing 1 hr after injection. Seen in after hour. Rx with systemic prednisone 30 mg qd x 2 and Atarax 25 mg qid. 2/26/10 visit - fading uticaria / macular rash leg.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381809-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Mar-2010	03-Mar-2010	0	04-Mar-2010	04-Mar-2010	CT		22-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Urticaria developed on L neck, chest.

Other Meds: None

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381820-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Mar-2010	01-Mar-2010	0	04-Mar-2010	04-Mar-2010	MI		04-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	PPV	MERCK & CO. INC.	1193Y	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0969Y	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3267JA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3052AA	0	Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP038AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pyrexia, Skin warm

Symptom Text: Left arm swollen, red, hot and fever of 103.8

Other Meds: Congentin Lamictal Paxil Adderal Xanax

Lab Data: none

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **381821-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Aug-2007	15-Aug-2007	0	04-Mar-2010	04-Mar-2010	VA		25-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0849U		Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0930U	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C277AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Abnormal behaviour, Chest pain, Chills, Confusional state, Constipation, Decreased appetite, Disturbance in attention, Fatigue, Headache, Insomnia, Irritable bowel syndrome, Migraine, Nausea, Oedema peripheral, Pain, Pain in extremity, Pallor, Personality change, Pyrexia, Staphylococcal infection, Suicidal ideation, Tinnitus, Vaccination complication

Symptom Text: Fever, chills, abd pain, headaches, and personality changes which were problematic for a period of several months after the immunizations. She was seen multiple times by neurologists and GI as well as by her PCP for follow up of these symptoms. ```PCP notes received 03/11/10 for DOS 08/15/07. Pt for routine physical. After immunization, Pt developed chills, epigastric pain, reflux, abdominal pain, HA, shaking and behavior changes. Pt came back to clinic and tx: Prilosec, Tylenol. On 08/17/07, Pt back for f/u visit and presented with epigastric pain, HA, pale. Fever had resolved. On 08/21/07, Pt presented with fatigue, loss of appetite and intermittent nausea. Assessment: constipation, HA and abdominal pain in epigastric area. Tx: Tylenol, Amitriptyline, Prilosec, Senokot, promethazine, glycerin suppositories. On 08/29/07, Pt presented with HA, difficulty sleeping, itchy eyes, and mentally fuzzy. Abdominal pain and appetite had improved. Tx: Depakote, Ambien; stopped Amitriptyline. On 08/31/07, Pt c/o HA, stomachache, nausea, body aches, low back pain, leg and arm numbness, hallucinations, and vomiting. Assessment: insomnia, HA, epigastric abdominal pain and neck pain. Ambien discontinued. On 09/04/07, Pt c/o abdominal pain, HA, muscle aches, vomiting. Assessment: insomnia, HA, epigastric abdominal pain. On 09/11/07, Pt c/o HA, vomiting, abdominal discomfort. Assessment: insomnia, HA, epigastric abdominal pain. tx: Prednisone started and Tylenol stopped. On 09/14/07, Pt c/o HA, fatigue, stomach pain and chest pain. Assessment: persistent HA, adjustment rxn, possible reaction to immunization, Prednisone rxn. On 09/17/07, Pt had neurology consult and exam revealed hemicrania HA. Impression: adverse rxn to vaccine probably in the territory of a septic meningitis, and more frequent migraines. Tx: Tylenol with Butalbital, Depakote, Diclofenac. On 09/18/07, Pt seen by PCP and reported HA and abdominal aches had improved. Assessment: prolonged atypical migraine likely initiated by immunization injections. On 10/

Other Meds:

Lab Data: complete metabolic profile, CK, ESR, aldolase, CBC, TSH, and MRI ```Labs and DX studies: T 100.8F oral, HR 102 bpm, BP 110/70 L arm sitting. MRI normal.

History: Chronic headaches Intermittent abd pain PAC's ```PMH: migraines for 2yrs. Allergies: NKDA.

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **381836-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	19-Jan-2010	19-Jan-2010	0	04-Mar-2010	05-Mar-2010	--	WAES1002USA03589	05-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer (the patient's husband) for the pregnancy registry for GARDASIL concerning "his wife (a 24 year old female), with no drug allergies who on approximately 19-JAN-2010 (about 5 weeks ago) was vaccinated with her first 0.5 mL dose of GARDASIL (lot number unspecified). There was no concomitant medication. Later she found out that she was approximately 2 weeks pregnant at the time of vaccination. A urine pregnancy test was performed. Her LMP was estimated to be approximately 04-JAN-2010. On 22-FEB-2010, at 7 weeks gestation, his wife had a miscarriage. His wife was admitted to the hospital (name and address unspecified) over night and she was released in the morning on 23-FEB-2010. The outcome was unknown. No further information is available.

Other Meds: None

Lab Data: urine beta-human, ?/?/10, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/4/2010)

Prex Vax Illns:

Vaers Id: 381837-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Nov-2007	01-Aug-2008	249	04-Mar-2010	05-Mar-2010	TX	WAES1002USA03728	25-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0263U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Bronchial hyperreactivity, Chest pain, Cough, Decreased appetite, Gait disturbance, Headache, Joint swelling, Muscular weakness, Myalgia, Oedema peripheral, Oropharyngeal pain, Pain in extremity, Photophobia, Presyncope, Syncope

Symptom Text: Information has been received from an office Manager concerning a 15 year old female with asthma and bronchitis, and a history of upper gastrointestinal pain and reflux, and no known allergies, who on 26-NOV-2007 was vaccinated with the first standard dose of GARDASIL, IM. The vaccination dates of the second dose and the third dose were not reported. Concomitant therapy included montelukast sodium, albuterol and PREVACID. In August 2008, after completing the GARDASIL series the patient experienced general muscle weakness, muscle pain, leg pain, leg swelling and syncope. The patient had difficulty walking due to the leg swelling. She sought medical attention via office visit. The patient was hospitalized, but reporter did not know how long the patient was hospitalized. Lab and Diagnostic Studies were done but the Office worker did not know exactly what studies were completed. Patient was seen by Cardiology and Neurology Specialist for intervention to to prevent serious criteria and all findings so far were negative. It was reported that the patient was still following up with various physicians and did not know if the symptoms had resolved at this time. General muscle weakness, muscle pain, leg pain, leg swelling, syncope and difficulty walking were considered to be other important medical events. Leg swelling and difficulty walking were considered to be disabling by the reporter, since the patient had difficulty walking due to the leg swelling. Additional information has been requested. ```PCP visit received 03/11/10 and 03/15/10 for DOS 11/26/07-09/03/09. Pt had no complaints. Pt received vaccination. On 09/10/08, Pt c/o reoccurring chest pain x 1wk. tx: Albuterol inhaler, ibuprofen. Impression: RAD. On 10/01/08, Pt with chest pain. Impression: chest wall pain, H Pylori. Tx: Prevacid. On 10/03/09, Pt went to ED for SOB, fainting, leg weakness, difficulty walking. Impression: syncope. On 12/02/09, Pt with sore throat, coughing. Neuro consult 09/03/09, Pt's exam normal. Assessment: syncope and collapse, HA, pho

Other Meds: albuterol; PREVACID; SINGULAIR

Lab Data: diagnostic laboratory, negative ```Labs and DX studies: H pilori, stress echo, CBC, sedimentation rate, CMP all normal. Brain CT, MRI normal.

History: Gastrointestinal pain; Gastrooesophageal reflux ```PMH: asthma, reflux. Allergies: PCN, orange.

Prex Illness: Asthma; Bronchitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381838-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-May-2009	20-May-2009	0	04-Mar-2010	05-Mar-2010	FR	WAES1002USA04008	05-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ28270		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Vestibular disorder

Symptom Text: Information has been received from a Health Authority (HA) (reference number ES-AGEMED-407217242) concerning a 14 year old female with no medical history reported who on 20-MAY-2009 was vaccinated IM with a 0.5 ml dose of GARDASIL (batch number NK18760, lot number NJ28270, site of administration not reported). It was reported that on the same date of vaccine administration, 20-MAy-2009, the patient developed a vestibular disorder (malaise with tendency to fall), according to the report, the patient was hospital admitted (admission and discharge dates were not reported). She was recovered on the following day, 21-MAY-2009. Vestibular disorder was the only adverse event coded in the Health Authorities report. Case reported as serious by the HA with hospital admission as criteria. Case is closed. Other business partner numbers include E2010-01239.

Other Meds: Unknown

Lab Data: unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381839-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Aug-2009	01-Sep-2009	1	04-Mar-2010	05-Mar-2010	FR	WAES1002USA04013	05-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Angioedema, Dyspnoea, Swelling face

Symptom Text: Information has been received from Health Authority (ES-AGEMED-789503439) concerning a 14 year old female patient who on 31-AUG-2009 was vaccinated with the second dose of GARDASIL (route, lot number and site of administration not reported). It was reported that 36 hours after vaccination, in September 2009 (exact date not reported), the patient presented face swelling and difficulty breathing. The patient was attended in the emergency room with corticosteroids as treatment. The patient recovered on an unspecified date. Angioedema was the only adverse event coded in the HA's report. Case reported as serious by the HA with other medically important condition as criteria. Other business partner number included: E2010-01236. Case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381840-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		04-Mar-2010	05-Mar-2010	FR	WAES1003USA00144	05-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervix carcinoma stage 0

Symptom Text: Case received from a health care professional on 19-FEB-2010. It was reported by a gynaecologist that a female patient of unspecified age received the complete immunization series with 3 doses of GARDASIL (lot#, injection sites and routes were not reported) on unspecified dates. Dose 1 and dose 2 of GARDASIL were given on unknown dates, toleration was not reported. Unspecified time post vaccination, the PAP smear was abnormal and showed class IV a. A sample was taken and laser treatment was intended. Upon medical review, the company upgraded the case to serious. Other business partner numbers included: E2010-01118. Further information were expected.

Other Meds: Unknown

Lab Data: Pap test, abnormal, showed class IV a

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381861-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	M	05-Feb-2010	19-Feb-2010	14	04-Mar-2010	05-Mar-2010	--		24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0314Y		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysgeusia, Ear pain, Facial palsy

Symptom Text: Approximately 2.5 weeks after administration of GARDASIL in normal, healthy adult male, age 26, patient described ear pain and taste changes -metallic taste on left side of tongue. Three days later patient has physical symptoms with a diagnosis of BELL's Palsy resulting in left facial paralysis. At the time of this report, symptoms have not resolved and patient has had physical symptoms of BELL's Palsy for 5 days.

Other Meds:

Lab Data: Evening of 2-19-10; patient experienced ear pain and change in taste sensation. Evening of 2-22-10; patient showed physical signs of BELL's Palsy as diagnosed by MD.

History: Medication allergy: minocycline; no smoking; social drinking, no significant medical history/disease states "tonsilectomy as toddler" no history of damage to either ear "no previous history of BELL's Palsy or other neuropathic complications

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **381913-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Feb-2010	26-Feb-2010	2	05-Mar-2010	05-Mar-2010	PA		29-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB287AB	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0216Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3012AASP	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Grand mal convulsion, Incoherent, Loss of consciousness, Staring, Tremor, Unresponsive to stimuli

Symptom Text: Parents awoke to child having a seizure at 0510 AM. Took child to Emergency Room. ER stated unsure that vaccine caused seizure-child going for further testing (EEG) 3/3/10 at Med. Center. ``` records received 03/08/10. Vaccination rec and ED rec. for DOS 02/26/10. Dx: seizure. ? adverse reaction to immunizations. Patient presented with c/o of seizure. Witness reported patient lost consciousness, was unresponsive, and experienced shaking all over. Patient was staring. Patient was confused after the episode. No prior history of seizures. Change of medications noted recent immunizations. Patient had no further seizure activity in ED dept. and was oriented x3. Patient stable and discharged. Plan: Follow-up with neurologist. ``` records received 03/09/10. Neurology outpatient consult. rec for DOS 03/04/10. Impression: Generalized convulsive epilepsy; without mention of intractable epilepsy. Chief complaint: New onset seizures. Parents found patient unresponsive with eyes looking straight. She had rhythmic shaking for 2-3 minutes. After the episode, the patient was incoherent. The patient had vaccinations 2 days prior to the event. Patient examined. Impression: Generalized convulsive epilepsy; without mention of intractable epilepsy. Record reflects that at this point unsure whether there was a link between immunization and the new onset seizure. Plan: Parents to administer Diastat if any seizure more than 4 min. and will hold off starting anti seizure meds for now, get emergent brain MRI and follow-up in 3 months.

Other Meds: None

Lab Data: CT scan ``` 03/08/10 CT head scan- normal, urine drug screen-negative, ALK phos-41 (L), WBC-3.9 (L), RBC-13.3 (WNL). ``` 03/09/10 LABS and DIAGNOSTICS: EEG- abnormal (epileptiform discharge over left frontal region). MRI brain (prominenc

History: Allergic to EES ``` 03/08/10 PMH: Lymph node resection. ```03/09/10 PMH: NKA, ADJ disorder w/ depression, sleep apnea, varicella uncomplicated.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **381988-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Oct-2007	18-Nov-2007	34	05-Mar-2010	08-Mar-2010	--		08-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Hypoaesthesia, Neck pain, Sensory loss

Symptom Text: MY NECK HURT FIRST. MY WHOLE BODY BEGAN BEING NUMB. A YEAR LATER IT FELT LIKE A NERVE WAS TRAPPED IN MY MIDDLE BACK. MY BODY STARTED JERKING WITH SUCH FORCE I WOULD BE THROWN FROM THE CHAIR I WAS SITTING IN. ANOTHER YEAR LATER I AM STILL NUMB. MY FACE, MY HANDS, EVERYWHERE - MY WHOLE BODY HAS LIMITED FEELING. I CAN STILL WALK AND TALK AND FUNCTION BUT I DONT FEEL HOT AND COLD AS WELL AS I USED TO AND I DONT FEEL PAIN LIKE I USED TO.

Other Meds: EVERYDAY CONTRACEPTIVE PILL.

Lab Data: MRI, CT SCANS ON CERVICAL SPINE AND BRAIN - SHOWED NOTHING. DOCTORS TOLD ME I AM COMPLETELY FINE.

History: NO

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Nov-2009	Unknown		05-Mar-2010	08-Mar-2010	AZ		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: (11/17/09) itching, hives pt did not report till next visit 3/4/2010.

Other Meds: No current meds

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382019-1** **Related reports:** 382019-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Feb-2010	22-Feb-2010	7	07-Mar-2010	08-Mar-2010	IN		25-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Headache, Loss of consciousness, Neck pain, Syncope

Symptom Text: Syncompal episode- daily. ```03/09/10, 03/10/10, and 03/11/10 received MD records for 02/24-03/04/10 as dates of service. Final Dx: Syncope and collapse, Headache. Presented to PCP with c/o intense headaches, was getting ready for school and thinks passed out, woke up on bathroom floor, pt. doesn't remember how arrived on bathroom floor. Next day f/u with PCP on passing out, pt reports episodic event x2 today accompanied by headcahe with neck pain x 5 days, unrelieved by OTC meds. To f/u 2-3 days. Reports falling in shower x 2, first time fell on forehead and second time hitting occipital region of head, pt verbalizes 8 episodes of syncope. Describes symptoms as passing out with unknown duration of syncopal episode. .

Other Meds:

Lab Data: Negative Holter, ECHO, CT of head, MRI of head and EEG Negative CBC, CMP, TSH. ```03/09/10, 03/10/10, and 03/11/10 received MD records for 02/24-03/04/10 as dates of service. Labs & Diagnostics: Ct head, normal. EEG, normal. Transthoraci

History: None. ```03/09/10, 03/10/10, and 03/11/10 received MD records for 02/24-03/04/10 as dates of service. PHM: Received Gardasil 02/15/10, 10/28/09 and 08/21/09

Prex Illness: No

Prex Vax Illns:

Vaers Id: **382019-2** **Related reports:** 382019-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Feb-2010	21-Feb-2010	2	15-Mar-2010	15-Mar-2010	IN		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Headache, Loss of consciousness, Menstruation irregular, Muscle spasms

Symptom Text: Blackout daily, headaches that don't go away, stomachaches cramps from hell, irregular periods "war in my head & storm in my body. Still having headaches daily

Other Meds: None

Lab Data: BRAIN MRI/CAT SCAN/ECHOHEART, HEART MONITOR, EEG, Blood test, chrio care due to falls in shower from black outs

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **382032-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Oct-2007	17-Oct-2007	0	08-Mar-2010	09-Mar-2010	FR	WAES1001USA01331	09-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Crohns disease, Dizziness postural, Fall, Head injury, Headache, Hypotension, Incorrect route of drug administration, Loss of consciousness, Malaise, Nausea, Presyncope, Vertigo

Symptom Text: Information has been received from a physician concerning an adolescent female patient aged 14 or 15 year old with no relevant medical history who in October 2007, was vaccinated with the first dose of GARDASIL (batch number not reported). In December 2007, i.e. two months after vaccination, the patient experienced malaise, vertigo, nauseas, loss of consciousness, cephalgia, and hypotension at 10/6. The patient was hospitalized. Vagal malaise was diagnosed. The patient recovered on an unspecified date. Follow up information received from the physician indicated that it was a case of misuse. The PV form and hospital report were provided. The patient was 15 years old at the time of the events. The patient received the first dose of GARDASIL subcutaneously (instead on intramuscularly as recommended) in the left arm on 17-OCT-2007. the patient has concomitant medication with TRINORDIOL. The patient experienced her vagal reaction on 10-DEC-2007. The event lasted 10 minutes and was reported as mild and not serious by the physician. The patient was seen at the emergency department (ED) on 10-DEC-2007 at 07:31 AM. In the corresponding report, it was specified that the patient had a history of pyelonephritis on malformative urinopathy with spontaneous resolution, tonsillectomy and adenoidectomy. The report stated that on 10-DEC-2007 on waking up the patient experienced a dizzy sensation difficult to describe with nausea followed when she got up by a fall with head injury and loss of consciousness for about 20 seconds. The event recurred a few minutes later. She also had persisting occipital and right-sided cephalgia. On arrival at the ED, her blood pressure was 109-65 mmHg, a pulse of 87 bpm and temperature of 37.2 C degrees. Clinical examination she had no vestibular nor cerebellar syndrome, cranial nerves were "Ok", pupils were symmetric and reactive. No neck stiffness was found, no photophobia, nor phonophobia. The patient has no sensory- motordeficit. Cardio-pulmonary examination found regular heart sounds, no murmur,

Other Meds: TRINORDIOL

Lab Data: Blood pressure measurement, 01?Dec07, 10/6, hypotension; blood pressure, 10Dec07, 109-65 mmHg; physical examination 10Dec07, normal vital signs/apyretic; neurological examination, 10Dec07, no vestibular, nor cerbellar syndrome, cranial nerv

History: Pyelonephritis; tonsillectomy; adenoidectomy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382033-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	26-Feb-2010		08-Mar-2010	09-Mar-2010	CA	WAES1003USA00007	09-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Cervix carcinoma

Symptom Text: Information has been received from a medical assistant concerning his/her 21 year old niece who on an unspecified date was vaccinated with third dose of GARDASIL (dose, route and lot number not reported). After getting all the three doses of the vaccine, the patient was diagnosed with cervical cancer on 26-FEB-2010. The medical assistant stated that the patient was diagnosed with a different type of HPV type that did not covered the GARDASIL vaccine. The patient sought unspecified medical attention. Cervical cancer was considered to be immediately life-threatening by the reporter. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382037-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Feb-2010	24-Feb-2010	0	08-Mar-2010	09-Mar-2010	FR	WAES1003KOR00007	09-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotension, Loss of consciousness

Symptom Text: Information has been received via a business partner company from a physician concerning a 16 year old female who on 24-FEB-2010 was vaccinated with the first dose of GARDASIL. On 24-FEB-2010 the patient experienced transient hypotension and loss of consciousness for few seconds. The patient lay down to rest, and her blood pressure were measured for 20 to 30 minutes interval. After about 3 hours the patient was stabilized and her blood pressure was normalized. It was reported that the expiration date of the vaccine was 02-APR-2010. Upon internal review in the business partner company, transient hypotension and loss of consciousness were considered to be other important medical events. The causality with GARDASIL was not reported. Additional information is not expected.

Other Meds: unknown

Lab Data: blood pressure measurement, 24Feb10, 40 mmHg.

History: unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382041-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Feb-2010	15-Feb-2010	0	08-Mar-2010	08-Mar-2010	NC		29-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: per mom pt has been having recurring HA since recieving gardsil #1

Other Meds:

Lab Data: none noted

History: none noted

Prex Illness: none noted

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382049-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Mar-2009	15-Apr-2009	16	08-Mar-2010	08-Mar-2010	FL		23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2614AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0940X		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Abdominal pain, Abdominal pain upper, Alopecia, Amnesia, Arthralgia, Autoimmune disorder, Cellulitis, Chest pain, Constipation, Decreased appetite, Dizziness, Fatigue, Food allergy, Headache, Helicobacter infection, Infectious mononucleosis, Lactase deficiency, Migraine, Nausea, Neck pain, Pallor, Temperature intolerance, Vomiting, Weight decreased

Symptom Text: Nausea HA neck pain wt loss chronic fatigue hair loss memory loss chest pain. Auto immune dg Hpylori x 2 Dizzy since 1st vaccine 3/09. ```PCP medical records received 3/10/10. Service dates 3/30/09 to 2/23/10. Assessment: H. pylori infection. Mononuceosis. Patient presents on day of immunization with itching, sneezing, congestion and c/o painful menstrual cycle. Returns 4/15/10 with cellulitis of left arm improved. Later complains of stomach ache and nausea. Weight loss, appetite decreased. Mononucleosis. Stomach pain continues. H. pylori infection. Dizzy, pale, hair loss, headache, cold intolerance. Food allergy. ```Neurology consult records received 3/15/10. Service date 1/20/10. Assessment: Migraines Patient complains of pressure/throbbing headaches without clear trigger or pattern. Patient shows no focal neurological symptoms or signs of degenerative process. ```Rheumatology consultation records received 3/15/10. Service dates 7/2/09 to 10/5/09. Assessment: No clinical evidence of scleroderma or CREST syndrome. Patient presents with concerns regarding abdominal discomfort and elbow pain. Patient is assymptomatic. ```Gastroenterology consultation records received 3/19/10. Service dates 7/2/09 to 2/15/10. Assessment: Recurrent abdominal pain, nausea. marked fecal retention. Frequent school absenteeism. Lactase deficiency. Patient presents for evaluation of nausea, vomiting, abdominal pain. Epigastric pain is postprandial in nature. Weight loss. Later related that the stomach ache develops on school days at 11 AM when she is a teaching assistent - others in the office at that time are 'mean'. During the next period she eats lunch with friends and the abdominal pain resolves. Constipation. Palpable stool in left lower and left upper quadrants. ```Note: 2nd HPV Lot# 0440X administered 6/5/09, 3rd HVP Lot# 13504Y given 11/13/09.

Other Meds:

Lab Data: EEG, CT-brain, endoscopy; bld wkup. ```LABS and DIAGNOSTICS: Hemoccult (+). EBV IGM 2.1 AI (H). H. pylori 0.93 (Equivocal). Anti-Centromere B Antibodies >8.0 AI (H). CBC - RBC 3.69 x10E6/uL (L) HGB 11.1 g/dL (L) HCT 32.4% (L). EEG - WNL. A

History: ```PMH: Allergies to Nasonex. Recent chest pain with exercise, cleared by cardiologist. Exercise induced asthma.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382063-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	24-Feb-2010	26-Feb-2010	2	08-Mar-2010	08-Mar-2010	TN		16-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037AA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2907BA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Skin warm, Swelling

Symptom Text: 6 1/2" x 5 1/2" area of swelling, redness, warm to touch.

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 382085-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Jan-2009	22-Jan-2010	368	08-Mar-2010	08-Mar-2010	NC		24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	057SX	0	Left arm	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Fatigue, Hypertension, Hypertriglyceridaemia, Micturition urgency, Nausea, Pollakiuria, Postural orthostatic tachycardia syndrome, Skin papilloma, Syncope, Urinary tract infection

Symptom Text: Started with weakness and fatigue progressed to high blood pressue and fainted for the first time on 2/28/2009. Has been diagnosed with Postural Orthostatic Tachycardia Syndrome. ```PCP medical records received 3/9/10. Service dates 1/29/10 to 3/9/10. Assessment: UTI. Patient presents with 4-5 days of urinary frequency and urgency. Fatigue, nausea. Later presents with viral wart on thigh. Hypertriglyceridemia.

Other Meds: none

Lab Data: Postural Orthostatic Tachycardia Syndrome, sweat test and tilt table tests have been done along with EKG testing. ```LABS and DIAGNOSTICS: Urinalysis - Leukocytes moderate, Blood moderate. Urine culture (+). DLDL 104 MG/DL (H) CHOL/HDL Rat

History: none. ```PMH: Headaches. Hyperlipidemia. Deletion of SHOX gene. Short stature. Eye corrective surgery.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **382122-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Mar-2010	08-Mar-2010	0	08-Mar-2010	09-Mar-2010	GA		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope, Tremor

Symptom Text: Stood up from mtrs lap, with 1 min after vaccination pt fainted, caught before hitting floor by nurse. while lying on floor, pt experienced violent head shaking of arm less than 5 secs. BP 100/60, coke given alert within 1 min left within 30 min.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns: Fainting~Varicella (no brand name)~2~12.00~Patient

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382159-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Mar-2010	03-Mar-2010	0	09-Mar-2010	09-Mar-2010	AZ		09-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B036BA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0652X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3053AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Mobility decreased, Nausea, Pruritus, Rash

Symptom Text: Became faint about an hour after getting the shot; later began feeling itchy and a rash-shortness of breath, nausea and said she couldn't lift her arm. Seen in ER at 11pm-shot received in ER to cover the rash, etc.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **382163-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Mar-2010	03-Mar-2010	0	09-Mar-2010	09-Mar-2010	VA		16-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Gave client vaccine; she denied any sexual activity since starting DMPA 12/09. Found out approx 20 min later that client had + UPT when preparing to give 2 DMPA injection.

Other Meds:

Lab Data: UPT +, Contraindication for vaccine.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382188-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	M	01-Mar-2010	07-Mar-2010	6	09-Mar-2010	09-Mar-2010	NC		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	104044P1	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1061U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Swollen lymph node under L axilla

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382194-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Mar-2010	Unknown		09-Mar-2010	09-Mar-2010	CA		09-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3048AA	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1129Y	1	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3250AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1013Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Injection site warmth

Symptom Text: Right arm deltoid swollen warm to touch (9cm x 9cm swelling).

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **382202-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Jan-2006	30-Jan-2010	1462	09-Mar-2010	09-Mar-2010	NM		09-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Pain

Symptom Text: Pt had redness and itching at vaccination site LA and then increasing pain. SMZ-TMP Dg #20 1 tab PO BID x10 day given.

Other Meds: none

Lab Data: none

History: allergy to AMOXICILLIN/bad rash

Prex Illness: none

Prex Vax Illns:

Vaers Id: 382216-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Sep-2008	20-Jan-2010	497	09-Mar-2010	10-Mar-2010	LA		10-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	063X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Body temperature increased, Headache, Hypoaesthesia, Muscular weakness, Paraesthesia, Rash erythematous, Weight bearing difficulty

Symptom Text: Numbness, paresthesias and weakness in lower extremities. Erythematous rash lower extremities. Difficulty bearing weight. Lower back pain, headache, low grade temperature.

Other Meds: Lexapro; Topamax; Loestrin

Lab Data: MRI - brain, upper and lower spine, normal; Lumbar puncture, normal; EMG-Nerve conduction study - Slow L Sural Nerve.

History: Migraine headaches

Prex Illness: Motor and sensory deficit in extremities.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382225-1** **Related reports:** 382225-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Apr-2008	22-Apr-2008	7	09-Mar-2010	09-Mar-2010	KS		10-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Arthralgia, Convulsion, Dizziness, Fatigue, Mood swings, Nausea, Paraesthesia, Syncope, Vomiting

Symptom Text: Extreme Fatigue, dizziness, nausea, fainting, seizures, vomiting, hair loss, joint pain, tingling in toes and fingers, mood swings. Have seen pediatrician, neurologist, endocrinologist, psychiatrist, cardiologist. Have had blood tests, cat scans, upper and lower GI.

Other Meds:

Lab Data: See above tests

History: seasonal allergies

Prex Illness: none

Prex Vax Illns:

Vaers Id: **382225-2 (S)** **Related reports:** 382225-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2008	01-Sep-2009	518	10-Mar-2010	11-Mar-2010	KS	WAES1003USA00590	11-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Amnesia, Anxiety, Cardiac arrest, Constipation, Convulsion, Diarrhoea, Dizziness, Fatigue, Headache, Hypoaesthesia, Laboratory test, Nausea, Photosensitivity reaction, Syncope, Vomiting

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter who by April 2008 was vaccinated with all three doses of GARDASIL (Lot# not reported). In September 2009, the patient experienced fatigue, seizures, headaches, nausea, throwing up, dizziness, numbness of the lower extremity of the toes and feet, memory loss, diarrhea, constipation, had fainted three times and had photosensitivity. It was reported that the patient had been in and out of the hospital (name and address not specified) since September 2009. It was also reported that in October 2009, while at college, the patient had a tilt table test done to check her blood pressure and during this procedure she had a seizure, her heart stopped and they had to do compressions. The patient's mother also mentioned that the patient had three seizures since then and she had seen a neurologist a neurologist, psychologist, and an endocrinologist. Multiple tests (unspecified) have been performed, with no results provided. The patient had to drop out of college and was put on some medication to help with the anxiousness she was experiencing. The reporter mentioned that her daughter had been taken off of all medication. At the time of the report, the patient had not recovered. Upon internal review seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: tilt test, 10/??/09, no results provided; blood pressure, 10/??/09, no results provided

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **382228-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.1	F	28-Apr-2008	29-Jan-2009	276	09-Mar-2010	10-Mar-2010	--	WAES0805USA00511B1	10-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ankyloglossia congenital, Drug exposure during pregnancy, Tongue tie operation

Symptom Text: Information has been received from a nurse for the Pregnancy Registry for GARDASIL and pediatric medical records concerning a female infant whose mother in approximately November or December 2007, was vaccinated with her first dose of GARDASIL (lot# not reported). In February 2008, her mother was vaccinated with her second dose of GARDASIL (lot# not reported). On 28-APR-2008 her mother was vaccinated with her third dose of GARDASIL (lot# not reported) and found out that she was pregnant. The mother's LMP was 28-MAR-2008. The pregnancy was confirmed on an unspecified date by a positive pregnancy test and complete bloodwork. Concomitant therapy included allergenic extract (allergy shot once a month). On 26-DEC-2008, the female infant was delivered via cesarean section with Apgars of 9 & 9 at 1 and 5 minutes respectively. On 29-JAN-2009, at 4 weeks well check, it was noted the infant was tongue tied. The infant was vaccinated with a second dose of hepatitis B vaccine (manufacturer unknown). The mother returned in February 2009 for her postpartum visit and she was breastfeeding the baby and there were "no problems" for her or the baby. She added the notes from the hospital and the office after the birth had no indication there were any problems. On 04-MAR-2009, at 4 month well check, the infant was vaccinated with a first dose of DT, ACTHIB, IPOL, PREVNAR (MSD). On 06-MAY-2009, at 2 month well check, the infant was vaccinated with the second dose of DT, ACTHIB, IPOL, PREVNAR and ROTATEQ (MSD) and tongue clip was performed. The infant's ankyloglossia was considered a congenital anomaly. The mother's experience has been captured in WAES # 0805USA00511. No further information is available. All medical records will be provided upon request.

Other Meds: Unknown

Lab Data: Apgar score, 9&9 at 1 and 5 minutes respectively

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382229-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Nov-2009	12-Nov-2009	0	09-Mar-2010	10-Mar-2010	VA	WAES1003USA00235	10-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Feeling hot, Pruritus generalised

Symptom Text: Information has been received from a medical assistant concerning a 19 year old female with no pertinent medical history and had an allergy with BIAXIN who on 08-SEP-2009 and 12-NOV-2009 was vaccinated intramuscularly with the first and second 0.5 mL dose of GARDASIL (dose 1 LOT# 0702X and dose 2 LOT# 0702X). There was no concomitant medication. Three hours after vaccination, the patient experienced body itching and body heat. At five hours after vaccination, the patient experienced chest pain and went to the emergency room. Subsequently, on an unspecified date the patient recovered from body itching, body heat and chest pain. The reporter considered the body itching, body heat and chest pain to be other important medical event due to the patient possibly received oxygen in the emergency room. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **382230-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Sep-2009	01-Sep-2009	0	09-Mar-2010	10-Mar-2010	FR	WAES1003USA00306	10-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphonia

Symptom Text: Initial information has been received from a pharmacist concerning a 23 year old female patient who received an injection of GARDASIL (Lot# and batch# not reported) in September 2009. 15 days later, she presented with aphonia. She was seen by her doctor and an ear-nose-throat specialist who could not find an explanation for the event. At the time of reporting, the patient had recently recovered but had remained aphonic for several months. The event of aphonia was considered to be an other important medical event. Other business partner numbers include E2010-01303. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382233-1** **Related reports:** 382233-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	M	09-Mar-2010	09-Mar-2010	0	09-Mar-2010	10-Mar-2010	CA		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1329Y	1	Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3356AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1013Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Lacrimation increased, Nasal congestion, Rash generalised

Symptom Text: @ 10:38 AM FELT WATERY EYES, NASAL CONGESTION PT USED HIS OWN INHALER AT THIS TIME 2 PUFFS.THEN MOM TOLD ME TO COME SEE HIM. AT THIS TIME THE PATIENT WAS RED RED AND A RASH HAD BEGUN TO COVER HIS BODY @ 10:43 AM WAS GIVE IM BENADRYL PER DR. GIVEN BY RN. @ 11:15 AM WAS GIVEN 0.4 CC EPPIE BY RN PER DR. @ 11:25 AM WAS GIVEN ALBUTROL BY NEB PER DR. @ 11:30 GIVEN 60 MG OF PREDNISONE BY DR.

Other Meds: ALBUTEROL

Lab Data:

History: ALLERGIES TO MILK AND HORSE SERUM

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **382233-2** **Related reports:** 382233-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	M	09-Mar-2010	09-Mar-2010	0	17-Mar-2010	18-Mar-2010	--	WAES1003USA01463	18-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
TDAP	SANOFI PASTEUR	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Swelling

Symptom Text: Information has been received from a registered nurse concerning an 18 year old male patient with asthma, milk allergy who on 09-MAR-2010 was vaccinated with the second dose of VARIVAX (Merck) (lot# not reported), the first dose of GARDASIL (Merck) (lot# not reported) and the second dose of ADACEL. On 09-MAR-2010, 8 minutes later the patient experienced an allergic reaction and used his inhaler. Eventually the patient was administered BENADRYL IM and then the patient developed swelling all over his body. He was next treated with an EPIPEN. At the time of this report, the patient's outcome was unknown. It was reported that the patient has a history of chronic conditions of asthma and milk allergy. He has been previously hospitalized with complications related to milk allergy and asthma. Upon internal review, allergic reaction and swelling all over his body that were treated with EPIPEN were considered to be other important medical events. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Hospitalisation

Prex Illness: Asthma; Milk allergy

Prex Vax Illns:

Vaers Id: **382238-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Feb-2010	12-Feb-2010	0	09-Mar-2010	10-Mar-2010	NM		10-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Fatigue, Heart rate increased, Pallor

Symptom Text: Dizziness,fast heart beat, weakness, paleness, really tired.

Other Meds: none

Lab Data: blood lab-fine

History: anemia,low-blood pressure.

Prex Illness: cold

Prex Vax Illns:

Vaers Id: **382240-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Apr-2007	25-Apr-2007	1	09-Mar-2010	10-Mar-2010	NY		26-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1265U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Arthroscopy, Decreased appetite, Diarrhoea, Fatigue, Headache, Insomnia, Joint swelling, Lactose intolerance, Migraine, Nuclear magnetic resonance imaging brain normal, Oedema peripheral, Patellofemoral pain syndrome

Symptom Text: intense abdominal pains, diahrrhea, headaches, migraines, loss of appetite, fatigue and moderate to intense join pain for months and now years since vaccinations. did get hpv #1 and vairvax on same day - previous report submitted (e42249 vares file) din't have the hpv vaccination recorded. ```GI consult received for DOS 06/21/07, 08/24/07, 12/12/07. Pt presented with diarrhea and abdominal pain since 04/07. Pt developed lactose intolerance and RUQ pain, and diarrhea after eating. Pt tx: lactose free diet, Immodium, Allegra, Xifaxin, Lactaid. Assessment: diarrhea and abdominal pain. On 12/20/07, Pt seen by infectious disease specialist and Pt c/o HA, leg pain, stiff neck, myalgias. Assessment: no infection found, but diarrhea likely due to lactose deficiency. On 12/28/07, Pt seen by GI again for HA and abdominal pain. Assessment: likely abdominal pain associated with migraines. Tx: NSAIDs. ```Neuro-ophthalmology consult received 03/15/10 for DOS 02/14/08. Pt c/o HA and GI symptoms. Impression: L parietal HA likely migraine process that runs in family, fatigue from lack of sleep. ```Orthopedic consult received 03/18/10 for DOS 07/18/08. Pt c/o R hand and L knee swelling. Impression: soft tissue strain of R hand, L knee swelling. On 09/03/08, Pt was seen again and impression L knee pain likely due to inflammatory response. On 03/09/09, 03/17/09, 04/01/09 Pt injury of L elbow, but no structural damage. Impression: L elbow soft tissue contusion. 12/15/09 and 12/23/09, Pt c/o chronic B knees pain. Impression: L knee patellofemoral syndrome, plica. 02/11/10, Pt underwent arthroscopy L knee and tolerated it well.

Other Meds:

Lab Data: numerous tests from pediatrician, pediatirc g/i specialists, orthopaedic dr, neurologist and rhuematologist ```Labs and DX studies: H Pylori test positive. Endoscopy normal. Celiac and RAST tests negative. Intestinal biopsy: lactose defi

History: ```PMH: asthma, HA, L eye vision problems. Allergies: none.

Prex Illness: no, but had recently had stomach bug, had thought was recovered

Prex Vax Illns:

Vaers Id: **382256-1** **Related reports:** 382256-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Mar-2010	08-Mar-2010	0	10-Mar-2010	10-Mar-2010	ND	ND1014	10-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Muscular weakness, Neck pain, Visual impairment

Symptom Text: After Gardasil injection, pt became faint. Pt was put in Trendelenberg with a cool cloth on forehead. After 10 min complained of pain in back of neck with vision changes. Stated vision going in and out. Arms felt like jello. Consulted Dr. After he examined pt, an ambulance was called to take patient to the ER. A spinal tap and CT scan of brain was done, which was normal. Pt was discharged with pain meds.

Other Meds: None

Lab Data: Ct scan, spinal tap, CBC, comprehensive panel, pg test- all normal.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **382256-2** **Related reports:** 382256-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Mar-2010	08-Mar-2010	0	16-Mar-2010	16-Mar-2010	ND		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Neck pain, Syncope, Visual impairment

Symptom Text: After GARDASIL injection, pt became faint. Pt was put in trendelenburg with a cool cloth on forehead. After 10 min, complained of pain in back of neck with vision changes. Stated vision going in and out. Arms felt like jello. Consulted doctor. After he examined pt, an ambulance was called to take pt to the ER. A spinal tap and CT scan of brain was done, which was normal. Pt was discharged with pain meds.

Other Meds: none

Lab Data: CT scan; spinal tap; CBC, comprehensive panel; PG test, all normal.

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382258-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Mar-2010	08-Mar-2010	0	09-Mar-2010	10-Mar-2010	CA		10-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0612Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Somnolence

Symptom Text: Patient got very sleepy after 20 mins. Was okay prior.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382260-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	03-Mar-2010	03-Mar-2010	0	10-Mar-2010	11-Mar-2010	FR	WAES1003PHL00005	11-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Heart rate decreased, Syncope

Symptom Text: Information has been received from a physician concerning a patient who on 03-MAR-2010 was vaccinated with GARDASIL. No concomitant medications were reported. On 03-MAR-2010 the patient experienced fainting and low pulse rate and was hospitalized. The patient was under observation at the time of the report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **382263-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	19-Mar-2008		10-Mar-2010	11-Mar-2010	FR	WAES1003USA00114	11-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0138U		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Autoimmune thyroiditis, Convulsion, Lethargy, Menstruation irregular, Polycystic ovaries, Syncope, Type 1 diabetes mellitus

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Details Form concerning a 16 year old female who in 2007 was vaccinated with three doses of GARDASIL (lot# 655742/0138U, batch# J0798; lot# 655742/0138U, J0800; batch# "J124") as part of school vaccination. Approximately 3 months post vaccination, the patient became very lethargic and also developed irregular menstruation. On 19-MAR-2008, the patient had a "seizure" at school and was seen at hospital where the diagnosis was a simple faint. However the patient developed further seizures leading to hospitalization for 3 weeks from the end of June 2008. In September 2008, the patient was diagnosed with polycystic ovary disease, Hashimoto's thyroiditis and Insulin-Dependent Diabetes Mellitus and was treated with metformin. Currently the patient was unable to attend school due to seizures and the need for constant supervision because of the risk of injury. At the time of the report, the patient's outcome was unknown. Her general practitioner was wondering about a possible link between her current symptoms (onset approximately 19-MAR-2008) and vaccination. The agency considered that convulsion, autoimmune thyroiditis, diabetes mellitus, menstruation irregular and polycystic ovaries were possibly related to vaccination with RECOMBIVAX HB. Onset date also reported as 21-AUG-2009. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **382265-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	01-Feb-2009	12-May-2009	100	10-Mar-2010	11-Mar-2010	FR	WAES1003USA00644	11-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hemiparesis, Hemiplegia, Inflammation, Multiple sclerosis, Paralysis

Symptom Text: Initially information has been received from Health Authority (reference # ES-AGEMED-332303440) concerning a 27 year old female who in February 2009 (exact date not reported), was vaccinated with the second dose of GARDASIL (0.5 ml, IM, batch #, site and route not reported). It was reported that after the second dose vaccination, the patient suffered cerebral inflammation picture and paralysis with right hemiplegia. The patient was taken to hospital (admission and discharge dates not reported). It appeared that the patient was finally diagnosed as scleraosis multiple. To be noted that the only adverse event coded in the report was hemiparesis, with start date on 12-May-2009 (cessation date not reported, outcome unknown). To be noted, HA coded only hemiparesis, and the onset was on 12-May-2009. In November 2008 (exact date not reported), the patient was vaccinated with the first dose of GARDASIL, (IM, batch # and site of administration not reported). It had not reported whether the patient presented any adverse events after the first dose or not. Case reported as serious by HA with hospital admission as criteria. Outcome was unknown. Case was closed. Other business partner numbers included E2010-01380. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382275-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	29-May-2008	30-May-2008	1	10-Mar-2010	10-Mar-2010	MN		10-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abasia, Dizziness, Vertigo

Symptom Text: The day after receiving GARDASIL patient had 12 hour episode of lightheadedness and vertigo & was unable to walk, normally due to vertigo. Same symptoms occurred after 2nd dose GARDASIL.

Other Meds: ORTHO CYCLEN

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **382283-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Feb-2010	25-Feb-2010	3	10-Mar-2010	10-Mar-2010	KY		10-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injection site anaesthesia, Paraesthesia

Symptom Text: On 2-25-10 pt woke up @ 540 AM c/o of numbness & tingling from L deltoid down arm to fingers. Now c/o of numbness & tingling comes & goes away. None today.

Other Meds: SUPRAX

Lab Data:

History:

Prex Illness: Gonorrhea

Prex Vax Illns:

Vaers Id: **382300-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Mar-2010	06-Mar-2010	1	10-Mar-2010	10-Mar-2010	NY		10-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Pruritus, Rash erythematous

Symptom Text: Rash on arms, trunk, legs small red raised bumps, hot really itchy.

Other Meds:

Lab Data:

History: Dogs allergy

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382326-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Mar-2010	09-Mar-2010	1	10-Mar-2010	10-Mar-2010	IL		11-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	43064AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0819Y		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Paraesthesia

Symptom Text: Erythema, tenderness, localized paraesthesia overlying injection site.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382349-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Oct-2009	Unknown		11-Mar-2010	11-Mar-2010	NC		11-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3246BA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP003AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: No adverse reation. Amberneshia Mintz was given vaccine for 18 years of age and older.

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **382350-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		11-Mar-2010	12-Mar-2010	--	WAES1003USA00463	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Angiogram abnormal, Blindness, Fundoscopy abnormal, Optic discs blurred, Retinal exudates, Scotoma, Slit-lamp tests abnormal, Visual field defect, Visual field tests abnormal, Visual impairment, Vitreous disorder

Symptom Text: Information has been received from a physician via a published article title as stated above and from a website. It was reported that a previously healthy 17 year old female with myopia presented central with central and paracentral dark shimmering spots in the vision of her left eye for 3 days diagnosed as multiple evanescent white dot syndrome. The right eye was normal. She had received her first GARDASIL and meningococcal (unspecified) vaccination 1 month before the onset of visual loss. She had no history of fever or flu-like symptoms within the past year. She denied any health problems and no family history of vision problems. She had no history of neurologic problems and no pain on eye movement. The patient's maternal grandmother had psoriasis and severe rheumatoid arthritis. Best-corrected Snellen Visual acuity was 20/20 in the right eye and 20/200 in the left eye. There was no afferent pupullary defect. Amsler grid testing of the left eye showed central and paracentral scotoma. Findings on slit-lamp examination were normal except for 1+ anterior vitreous cells in the left eye. Fundus examination of left eye showed slight blurring of the optic disc margin, loss of the foveal reflex, 1+ posterior vitreous cells, and rare small white spots in the macula and nasal periphery. Humphrey 30-2 visual field testing showed enlargement of the blind spot in the left eye. Fluorescein angiography of the left eye showed subtle hyperfluorescent spots corresponding to the white spots seen on fundoscopy. Optical coherence tomography of the left eye showed loss of normal architecture of the deep retina. Findings on examination and testing of the right eye were normal. The patient was HLA-B27-positive, but was not HLA-B51-positive. On follow-up examination 2 months after the initial evaluation, visual acuity had improved to 20/20 in the left eye and the Humphrey 30-2 visual field was normal. It was reported that the association of the patient's multiple evanescent white dot syndrome with the GARDASIL and meningococcal vaccine

Other Meds: Unknown

Lab Data: Ophthalmological exam, see narrative

History:

Prex Illness: Myopia

Prex Vax Illns:

Vaers Id: **382351-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Jan-2010	Unknown		11-Mar-2010	12-Mar-2010	TX	WAES1003USA00592	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Laboratory test, Pain, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a physician and a medical assistant concerning a 13 year old female patient who on 06-MAY-2009 was vaccinated with the first 0.5 ml dose of GARDASIL (Lot # 658282/0929U) concomitantly with a dose of MENACTRA (Lot # UF389AA). On 04-AUG-2009, the patient was vaccinated with the second dose of GARDASIL (Lot # 658282/0929U) and on 19-JAN-2010, the patient was vaccinated with the third dose of GARDASIL (Lot # 658282/0929U). According to the physician, after the patient received her third dose of GARDASIL, she reported that she was extremely sore and weak. The medical assistant reported that the patient had a physician's note to be out of school on 25-JAN-2010 and remained out of school for the rest of that week (until approximately 29-JAN-2010) for symptoms of being extremely sore and weak, it was also reported that the patient had another note to be out of school for symptoms of extremely sore and weak from 01-MAR-2010 to 12-MAR-2010 (also reported by the physician as "missed 2 months of school"). The physician also mentioned that the patient had "mild symptoms" following the first and second dose of GARDASIL (dates not reported). The medical assistant stated that the patient had not recovered. The patient sought unspecified medical attention. Diagnostic laboratories test were performed (not results provided). Upon internal review the patient remained out of school for symptoms of being extremely sore and weak, was considered disabling. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **382352-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		11-Mar-2010	12-Mar-2010	--	WAES1003USA00465	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Demyelination, Headache

Symptom Text: It was reported in a newspaper article that a 16 year old female patient on an unspecified date, was vaccinated with the second dose of GARDASIL. Subsequently the patient experienced a visual loss in the right eye and a left side headache. Over the next 24 hours, the patient's symptoms worsened to include her left eye and a more severe headache. Ten days after the second vaccine, the perfectly healthy patient was left almost totally blind. At the time of reporting, the outcome was unknown. The reporter stated that it was possible that human papilloma virus was the precipitant for the demyelinating event in the patient presented here. It was tempting to speculate whether there may be a specific immune mechanism initiated with human papilloma virus not yet identified, which resulted in not only acute demyelinating encephalomyelitis but also in an unusual clinical course that resulted in persistent visual loss. An expert who worked in the vaccine trials said that the majority of vaccine injuries actually occur in what she called the 'biologically plausible time frame' which was, she said, up to 42 days after the vaccine. Upon internal review, visual loss in the right eye and visual loss in the left eye were determined to be other important medical events. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **382353-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	16-Jun-2009	24-Jun-2009	8	11-Mar-2010	12-Mar-2010	FR	WAES1001USA03313	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Areflexia, Dysaesthesia, Epilepsy, Headache, Hypoaesthesia, Inappropriate schedule of drug administration, Neurological examination normal, No reaction on previous exposure to drug, Somnolence

Symptom Text: Case reported by Health Authority on 07-JAN-2010 under the reference number PEI2009024114. It was reported by a neurologist that a 27 year old female patient was vaccinated with a dose of GARDASIL (lot #, injection site and route not reported) on 16-JUN-2009. Concomitant therapy included (not specified) hormonal contraceptives for systemic use and ciprofloxacin (treatment of urinary tract infection in June 2009, exact date not reported). On 24-JUN-2009 the patient experienced left-sided hemihypaesthesia, headache, and drowsiness for approximated 5 weeks. The last examination performed on 17-AUG-2009 only revealed dysaesthesia of the left forearm. At the time of reporting to HA (02-SEP-2009) the patient had not recovered from dysaesthesia. Nothing was reported about any diagnostics, only " no changes of laboratory parameters" was mentioned. Previous vaccination with GARDASIL on an unspecified date was well tolerated. This file is closed. Follow up information was received on 02-MAR-2010. A hospital report and a neurological examination report were provided by the Health Authority. This case has to be upgraded. The patient was hospitalized from 08-JUL-2009 to 10-JUL-2009 due to left-sided hemihypaesthesia which occurred during a holiday in the evening of 24-JUN-2009. Investigations from a former examination were adjudged. Cranial magnetic resonance imaging (MRI) showed normal results, electroencephalography (EEG) showed epileptic like potentials. Treatment with VALPROAT had been started. At the time of hospitalization another EEG was carried out and showed no further epileptic like potentials. Additional to hemihypaesthesia absent abdominal reflexes were detected. Muscles reflexes were "agile" at both sides. Several examinations included electrophysiological, psychiatric, general physical and ECG showed normal results. CSF (cerebrospinal-fluid) cell count was increased with 12/ul. Blood sample from 08-JUL-2009 showed increase of thyroid stimulating hormone (TSH) with 6.27 ulU/ml (history of hypothyroidism). Other l

Other Meds: CIPROFLOXACIN; hormonal contraceptives

Lab Data: Orthopedic examination, 07Jul09, no pathological findings; electroencephalography, no further epileptic like potentials; magnetic resonance imaging, normal; electroencephalography, epileptic like potentials; psychiatric evaluation, normal;

History: hypothyroidism

Prex Illness:

Prex Vax Illns:

Vaers Id: **382354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	13-May-2009	13-May-2009	0	11-Mar-2010	12-Mar-2010	IL	WAES0906USA03411	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure increased, Caesarean section, Drug exposure during pregnancy, Failed trial of labour, Pregnancy induced hypertension

Symptom Text: Information has been received through the pregnancy registry for GARDASIL, from a registered nurse concerning a 21 year old female with no medical history or drugs allergies, who on 13-MAY-2009 was vaccinated with a dose of GARDASIL (lot # 661953/1130X). There was no concomitant medication. The patient is now pregnant, the pregnancy is normal to date; her LMP was 11-APR-2009. The patient had a urine pregnancy test. The patient sought medical attention through an office visit. Follow up information received on 30-JUN-2009 from a registered nurse stated that the patient was a female, who on 13-MAY-2009 was vaccinated with a first dose of GARDASIL (lot # 661953/1130X). Concomitant therapy included prenatal vitamins. It was also reported that the patient didn't have any previous pregnancies. Follow up information received from a physician indicated that the patient had a medical history of Rhesus antibodies negative. On 26-OCT-2009 the patient was given RHOGAM times 1 for RH negative and on 13-JAN-2010 the patient was placed on therapy with labetalol 100 mg twice a day for increased blood pressure. On 16-JAN-2010 at 39.6 weeks from her last menstrual period the patient gave birth to a normal baby boy who weighed 8.10; length 20. Due to failure to progress the patient had a C-section done. It was also reported that on an unspecified date the patient developed pregnancy induced hypertension. Upon internal review C-section due to failure to progress was determined to be an other important medical event. No further information is available.

Other Meds: RHOGAM; vitamins (unspecified)

Lab Data: Urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 4/11/2009); Rhesus antibodies negative

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382412-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	20-Feb-2010	20-Feb-2010	0	11-Mar-2010	11-Mar-2010	UT		11-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria, Urticaria

Symptom Text: Hives (small bumps) around injection. Site, down arms to hands and on back. Mom treated with BENADRYL with some relief. Spreading now to face (3/1/10).

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **382427-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	05-Jan-2010	06-Jan-2010	1	11-Mar-2010	12-Mar-2010	IL		16-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	01004	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Patient called office on 3-4-10 to cancel 2nd GARDASIL vaccine secondary to C/o all over body rash after 1st vaccine. Patient's rash started on arms then progressed to legs. No itching. Symptoms x5 days. Spontaneous resolution. Pt did not use any medication for symptom relief.

Other Meds: Tri-nessa; 1 Gram P.O. singled, Singled; Zithromax started 1-7-10

Lab Data:

History: Ceclor; Ceftin; Septra - Allergy -rash

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382433-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Feb-2010	24-Feb-2010	7	11-Mar-2010	12-Mar-2010	OH		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: 7 days after 3rd dose pt having dizzy episodes.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **382462-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Aug-2009	Unknown		11-Mar-2010	12-Mar-2010	KS	200903630	12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Hyperhidrosis, Myalgia, Nausea, Rash

Symptom Text: Initial information received on 21 August 2009 from a health care professional. A 15 year old female patient with an unknown medical history received MENACTRA in the right deltoid (lot number U2917AA) on 14 August 2009. Illness at the time of vaccination was not reported. On 14 August 2009, 8-10 hours post vaccination, the patient developed diffuse myalgia, fatigue, sweating, and nausea which lasted 36 hours. On 17 August 2009 the patient developed a rash. Recovery status was not provided. No further information provided. Follow up information received on 13 October 2009 from a health care professional. The route of administration MENACTRA vaccine was intramuscular. The patient also received a first intramuscular injection in the left deltoid of GARDASIL (Merck and Co., lot number 00874) and on 14 August 2009. Illness at the time of vaccination was none. Other medications were reported as none. Follow-up information received on 16 November 2009 from a healthcare professional. The patient was seen by a physician on 17 August 2009. No laboratory or diagnostic tests were performed. The patient recovered by 21 August 2009.

Other Meds:

Lab Data: No laboratory or diagnostic test were performed.

History: Unknown medical history, illness at the time of vaccination was not reported.

Prex Illness:

Prex Vax Illns:

Vaers Id: **382509-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	M	11-Mar-2010	11-Mar-2010	0	12-Mar-2010	12-Mar-2010	AZ		26-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353Y		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3021AA		Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3356AA		Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0950Y		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hyperhidrosis, Injection site erythema, Injection site pain, Musculoskeletal pain, Pain in extremity, Tinnitus, Tremor, Vision blurred

Symptom Text: L arm, shoulder pain, sweating, ringing in ears and shaking. ```3/17/10 Pediatric records received for date of service 3/1 1/10. Dx: S/p immunization reaction. After vaccines began shaking, sweating, blurred vision, ringing in ears, had pain in L arm. Redness to injection site, tenderness at injection site. Mild tremors in hands.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 382520-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Jul-2009	01-Jul-2009	0	12-Mar-2010	15-Mar-2010	TX	WAES1003USA00895	15-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Autonomic nervous system imbalance, Back pain, Gallbladder disorder, Migraine, Neck pain, Neuralgia, Syncope

Symptom Text: Information has been received from a healthcare worker concerning her 25 year old daughter who in July 2009, was vaccinated with her third dose of GARDASIL (lot # not reported). In approximately July 2009, after patient received her third dose of GARDASIL, she began to have adverse experiences which led to an emergency room visit and hospitalization. She started pain in the neck and back, nerve pain, autonomic dysfunction, chronic low blood pressure, gall bladder disease and possible gall bladder removal, vaso/vago syncope, and migraines. These adverse effects have been debilitating with her job. It was also reported that during the patient's hospitalization, her blood pressure "bottomed out", and her heart rate "skyrocketed". Unspecified laboratory tests were performed (results not provided). At the time of the report the patient was on a machine to monitor blood pressure. The patient was being treated by a cardiologist and by a nurse practitioner. The reporter stated that "these adverse events are still going on but have improved slightly". The reporter considered pain in the neck and back, nerve pain, autonomic dysfunction, chronic low blood pressure, gall bladder disease and possible gall bladder removal, vaso/vago syncope, and migraines to be immediately life-threatening, disabling and other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: blood pressure, chronic low blood pressure; blood pressure, blood pressure bottomed out during her hospitalization; cardiac monitoring, heart rate skyrocketed

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **382522-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	M	11-Feb-2009	11-Feb-2009	0	12-Mar-2010	15-Mar-2010	FR	WAES0905USA01428B1	16-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Congenital anomaly, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information was obtained on request by the company from the agency via a Public Case Details form concerning a male baby who was born from a mother who on 11-FEB-2009 (4.5 weeks after her last menstrual period) and 11-MAY-2009 (also reported as 12-MAY-2009) (17 weeks after her last menstrual period) was vaccinated with the first and second dose of GARDASIL vaccine respectively. Subsequently, the mother was found to be pregnant (WAES # 090USA01428). It was reported that the patient delivered a normal male child on 15-OCT-2009. The infant was born with a hypospadias. At the time of reporting on 30-NOV-2009, the infant's outcome as unknown. The hypospadias is a congenital anomaly. The reporter felt that hypospadias was possibly related to therapy with GARDASIL vaccine. The original source was not provided.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **382523-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Mar-2009	01-Mar-2009	0	12-Mar-2010	15-Mar-2010	FR	WAES0908USA00671	15-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breast feeding, Breech presentation, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer, for GARDASIL, a Pregnancy Registry product, concerning a 25 year old female with no relevant medical history who was vaccinated with the second dose of GARDASIL (batch number not reported) in March 2009 as she was pregnant. Her latest Menstrual Period dated back to 03-FEB-2009 and the date of delivery was estimated for 17-NOV-2009. Her dosage in iron was a little low. The pregnancy was spontaneous. Follow up information received on 09-MAR-2010 by telephone: The case which was not medically confirmed was upgraded to serious due to the seriousness criterion "other medically relevant", i.e. caesarean section. The patient's pregnancy was uneventful. She gave birth to a female baby on 18-NOV-2009 by caesarean section due to breech presentation. The baby was doing fine. She was breastfed. The patient had had no previous pregnancy. The third injection of GARDASIL was scheduled soon. No further information expected. Other business partner numbers include E200906179.

Other Meds: Unknown

Lab Data: Urine iron test, dosage in iron was a little low

History:

Prex Illness: Pregnancy NOS (LMP = 03Feb09)

Prex Vax Illns:

Vaers Id: **382524-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-Mar-2010	15-Mar-2010	NY	WAES1003USA00591	15-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a public health nurse who found out from a physician who in turn heard from an OBGYN concerning a female patient who on an unspecified date, was vaccinated with a dose of GARDASIL. On an unspecified date, the patient experienced seizure and paralysis. Follow up information has been received from the physician concerning a female who on unspecified date, was vaccinated with a dose of GARDASIL at her OBGYN physician's office. On an unspecified date, the patient experienced seizure and syncope (not paralysis as previously reported) after receiving the GARDASIL vaccination. At the time of the report, the outcome was unknown. Additional and conflicting follow-up information was received from a licensed practical nurse. According to the licensed practical nurse, the physician did not have a patient that had a seizure and syncope after vaccination with GARDASIL. Upon internal review, seizure was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **382541-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	22-Feb-2010	22-Feb-2010	0	12-Mar-2010	12-Mar-2010	MI		12-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonia, Immediate post-injection reaction, Unresponsive to stimuli

Symptom Text: Pt went limp and unresponsive for about 30-40 seconds immediately following 2nd Gardasil vaccination.

Other Meds:

Lab Data: Blood sugar and Blood pressure both checked.

History: None

Prex Illness: None reported

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382543-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Jan-2010	28-Jan-2010	0	12-Mar-2010	12-Mar-2010	MI		12-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1378 Y	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3058AA	0	Left leg	Intramuscular	
VARCEL	MERCK & CO. INC.	1113Y		Right arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049AA		Left arm	Intramuscular	
HEPA	MERCK & CO. INC.	0912Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness

Symptom Text: Pt passed out and fell approx 5 min after vaccinations were given. Pt reported not eating any foods prior to vaccinations.

Other Meds:

Lab Data: MD Eval. Vitals monitored Food/Drink given

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382567-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Mar-2010	02-Mar-2010	0	12-Mar-2010	15-Mar-2010	CA		15-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	C3438AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	13784	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3081AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Convulsion, Loss of consciousness

Symptom Text: My daughter received meningitis vaccine without immediate reaction, then a tetanus vaccine She was still fine. The she received the GARDASIL. She had a seizure, lost consciousness, drop in blood pressure. She was unconscious for about 15 sec.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **382618-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Feb-2010	15-Feb-2010	0	15-Mar-2010	15-Mar-2010	NY		15-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Hypotension, Nausea, Pallor, Tinnitus

Symptom Text: As patient was leaving, felt nauseous. Brought patient back into room. Very pale, diaphoretic, BP 73/44, hr 63. States her ears were ringing. Laid down for 20 more minutes, juice box given and finished. Ear ringing resolved, patient's color much improved. BP 88/59, HR 59. BP at 11:25 90/64 HR 65. Patient standing and walking with no issues. States feels much better. Left with mother.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382630-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Apr-2009	11-Apr-2009	1	15-Mar-2010	15-Mar-2010	FL		25-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysphagia, Neck pain, Pyrexia

Symptom Text: Vaccine HPV given on 4/10/09. Pt reported on 4/28/09 that she had pain in neck on side and had difficulty swallowing and fever next day of vaccine, on 4/11/09.

Other Meds: Birth control pills; Lactose solution

Lab Data:

History: Obesity; c/o large breast; Back pain

Prex Illness: Menstrual cramps

Prex Vax Illns:

Vaers Id: **382641-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Sep-2007	01-May-2008	241	15-Mar-2010	16-Mar-2010	FR	WAES1003USA00812	16-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1537F	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Anti-cyclic citrullinated peptide antibody, Arthralgia, Back pain, Blood creatinine normal, Blood immunoglobulin G normal, Blood lactate dehydrogenase normal, Blood urea normal, Blood uric acid normal, C-reactive protein normal, Connective tissue disorder, Dyskinesia, Dyspnoea, Gamma-glutamyltransferase normal, Gastritis, Gastrointestinal infection, Gastrointestinal mucosal disorder, Gastrointestinal tract mucosal discolouration, Hip dysplasia, Immunoglobulins normal, Joint effusion, Joint stiffness, Joint swelling, Musculoskeletal pain, Nausea, Pain, Restlessness, Reticulocyte count normal, Rheumatoid factor, Tonsillitis, Urticaria

Symptom Text: Information has been received from a health care professional on 02-MAR-2010 and additional information on 03-MAR-2010. It was reported by a gynecologist that a 14-year-old female patient received a complete vaccination series with 3 doses of GARDASIL into the deltoid muscle on 03-SEP-2007 (D1, lot #1537F, batch #: NF32810), on 05-NOV-2007 (D2, lot # 1537F, batch #: NF32810) and on 03-APR-2008 (D3, lot#: 0354U, batch number: NF58150). On 09-APR-2009 the patient reported that she experienced severe rheumatic symptoms (verbatim) shortly after the first dose. Further information received through the outpatient department's and hospital report on 03-MAR-2010. Family medical history: (information illegible). The patient was treated in a rheumatologic outpatient department since 07-MAR-2009 and was hospitalized from 05-MAY-2009 to 08-MAY-2009 (all results were summarized in one report). In May 2008, the patient experienced both-sided hip pain and was referred to an orthopedist who performed an MRI of the hip. It showed degenerative changes at the acetabulum (right side more than left) and a moderate articular effusion which was referred to arthritic activation at hip dysplasia. A surgical sanitation of the hip joints was suggested. After referring the patient to the surgeon a rheumatologic disease was suspected. A taken blood sample showed positive HLA-B27 antigens. She developed increasing hip pain, mild morning stiffness of both hips, painful temporomandibular joints and the opening of the mouth decreased to 2.5 cm. She reported, that the left ankle was often swollen, she suffered from knee pain when walking and pain in the lumbosacral area. Two months before admission the patient experienced tonsillitis and gastrointestinal infection. Additionally the patient used inlays and wore a dental splint. On 17-MAR-2009 physical investigation showed pain during flexion and extension of the hip joint (both-sided), dorsal extension and plantar flexion and opening the mouth (possible up to 2.5 cm). The same day special diagnost

Other Meds: Unknown

Lab Data: Ultrasound, 23Mar09, effusion of the left upper ankle joint; Physical examination, ??Apr09, showed pain-see narrative; Magnetic resonance imaging, 1??Apr09, see narrative; X-ray, 17Apr09, see narrative; Gastroscopy, 05?May09, see narrative;

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382645-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		15-Mar-2010	16-Mar-2010	FR	WAES1003USA01240	16-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Venous thrombosis

Symptom Text: Case received from a gynaecologist on 26-FEB-2010. A 22 year old female patient was vaccinated with an injection of GARDASIL (batch number not reported) on an unspecified date. Concomitant therapy included TRINORDIOL. The patient was subsequently hospitalized for one month due to thrombosis of the right ovarian vein. The outcome was not reported. Other business partner numbers included E2010-01492.

Other Meds: TRINORDIOL

Lab Data: unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 382665-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Dec-2009	19-Dec-2009	1	15-Mar-2010	15-Mar-2010	WV		15-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Chest pain, Diarrhoea, Dysuria, Gallbladder disorder, Headache, Myalgia, Nausea, Thyroid function test abnormal, Vomiting

Symptom Text: SEVERE HEADACHE, SHARP PAIN IN ABDOMEN, MUSCLE ACHES, JOINT PAIN, NAUSEA, VOMITING, CONSTANT LOOSE BOWEL MOVEMENTS, CHEST PAIN, BURNING AND PAINFUL URINATION, ELEVATED THYROID LEVELS, AND GALL BLADDER DYSFUNCTION

Other Meds: DEPO PROVERA

Lab Data: BLOOD WORK, CT SCANS, ULTRASOUNDS, GALL BLADDER ULTRASOUND AND HIDA SCAN, URINE CULTURE AND STOOL CULTURE

History: Patient had an ovarian cyst surgically drained from her right ovary on 12/7/2009.

Prex Illness: NONE

Prex Vax Illns: SEVERE HEADACHE~HPV (Gardasil)~1~12.75~Patient|SEVERE ABDOMINAL PAIN~HPV (Gardasil)~1~12.75~Patient|MUSCLE AND JOINT PAIN~HPV (Ga

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382668-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Jan-2010	15-Jan-2010	0	15-Mar-2010	15-Mar-2010	FL		15-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0669Y	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Syncope

Symptom Text: Patient fainted 5 minutes after injection for 5 seconds, vital sign b/p 83/52 respiration 20, pulse 55, o2 saturation 98% at first. Second set of vital signs 112/72 pulse 47,respiration 20, b/p 112/72. Third set of vital signs b/p 104/64, pulse 52. Patient transferred to ER for one hour observation on stretcher. Patient reported it was not the first time she fainted after blood draw.

Other Meds:

Lab Data: Vitals: blood pressure, pulse, respiratory rate, O2 saturation

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382699-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Mar-2010	11-Mar-2010	0	15-Mar-2010	16-Mar-2010	TX		16-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1538Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2872AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0249Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Loss of consciousness

Symptom Text: Client passed out 5 minutes after administering the immunization and hit the back of her head. Client was trasported to hospital via ambulance. Client also stated she was scared of needles.

Other Meds: Birth Control--Orthotricyclene

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 382732-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Mar-2010	09-Mar-2010	0	16-Mar-2010	16-Mar-2010	GA		25-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Haematuria, Injection site haematoma, Pyrexia, Vertigo

Symptom Text: Approximately 4 hours after GARDASIL injection (#2) developed severe joint pain, fever (100.5), vertigo, (small) bruise at injection site. Pos tr. hematuria.

Other Meds: ADVIL given on 3/9/10 in afternoon when symptoms started. After GARDASIL

Lab Data: UA and UCX sent to lab

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **382745-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Dec-2009	01-Mar-2010	62	16-Mar-2010	17-Mar-2010	--	WAES1003USA00593	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Headache, Hypersensitivity, Mass

Symptom Text: Information has been received from a neurologist concerning a 16 year old female patient who on an unspecified date, was vaccinated with a dose of GARDASIL (lot# not reported) at another health care providers' office. On 02-MAR-2010 the patient was admitted to hospital with severe headaches and increased fluid pressure in the head known as pseudotumor. 2 spinal taps were performed with pressure elevated both times. The patient was still in the hospital, and her pseudotumor persisted. The neurologist stated that the patient's mother was insisting pseudotumor was related to therapy with GARDASIL. Follow up information has been received from the neurologist concerning the patient who on 29-DEC-2009 was vaccinated with the first dose of GARDASIL. It was reported that the patient had a history of headaches prior to receiving GARDASIL and the complaint of headaches started on 30-DEC-2000. After the vaccination, the patient's headache became very severe. The patient also had a severe allergy (not specified) and the physician had "no idea if the patient's allergy was secondary to receiving GARDASIL. The patient had an appointment with the neurologist on 08-JAN-2010. On 01-MAR-2010, the patient was admitted to hospital. While in the hospital the patient had "two spinal taps to reduce the patient's fluid pressure" and was treated with steroid therapy. The patient was treated with another medication (name of medication not specified) and the patient had a severe reaction to the medication, which increased her fluid pressure. The neurologist stated that the patient was taken off all medications due to her reaction to the unspecified medication. The patient was discharged from the hospital on 06-MAR-2010 and had a scheduled follow-up appointment to see the neurologist. Additional information has been requested.

Other Meds: Unknown

Lab Data: Spinal tap, 03/02/10, 2 spinal taps performed with pressure elevated both times.

History:

Prex Illness: Headache

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382748-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	F	23-Apr-2009	23-Apr-2009	0	16-Mar-2010	17-Mar-2010	FR	WAES1003USA01419	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Infection

Symptom Text: Information has been received from a healthcare professional concerning a female neonate born via caesarean section who experienced an unspecified peripartum infection. Her mother, a 16 year old female patient, had received the second dose of GARDASIL (batch number not reported) on 23-APR-2009 (of linked case). The mother was vaccinated while pregnant. She delivered on 20-DEC-2009. Peripartum infection kept the patient hospitalized until 28-DEC-2009. At the time of reporting, the patient and her mother were well. No further information is expected. Case linked with serious case E2009-05719 (WAES 0907USA01036). Other business partner numbers include E2010-01538.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **382750-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Jun-2009	29-Jun-2009	21	16-Mar-2010	17-Mar-2010	FR	WAES1003USA01645	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthritis

Symptom Text: Initial case was reported on 09-MAR-2010 by Health Authority (HA ref. DK-DKMA-20094639). It was reported that a 12-year-old female patient with no concurrent illness reported was vaccinated with the first dose GARDASIL (i.m., batch number and site of administration not reported) on 08-JUN-2009. No concomitant medicine was reported. It was reported that the patient developed intermitting episodes of arthritis in the large joints 3 weeks post vaccination. It was reported that each episode of arthritis lasted for 3-5 days and that the patient was symptom free for 1 week, before the symptoms returned. It was reported that the patient had not recovered. The patient's arthritis was considered to be disabling by reporter. Other business partner numbers include E2010-0558. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382751-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Oct-2008	04-Jan-2009	89	16-Mar-2010	17-Mar-2010	FR	WAES1003USA01646	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Facial palsy

Symptom Text: Initial case was reported on 09-MAR-2010 by Health Authority (HA ref. DK-DKMA-20094699). It was reported that a 13-year-old patient was vaccinated with the second dose GARDASIL (i.m., batch number and site of administration not reported) on 07-OCT-2008. It was reported that the patient developed Bell's palsy on 04-JAN-2009. The patient was admitted to hospital on 05-JAN-2009. It was reported that lumbar puncture was negative for Borrelia (not further specified). The patient was discharged on 06-JAN-2009 and recovered on 20-JAN-2009. The patient had no concurrent disease and received no concomitant medicine. Other business partner numbers include E2010-01554. No further information is available.

Other Meds: None

Lab Data: Spinal tap, 05?Jan09, lumbar puncture was negative for borrelia

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **382752-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Aug-2009	01-Nov-2009	92	16-Mar-2010	17-Mar-2010	FR	WAES1003USA01652	17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Joint stiffness

Symptom Text: Information has been received from a health authority (local ref. # BS20100135 and BS10D0063) concerning a 14 year old female patient who had received a second dose of GARDASIL (lot #, batch # and site of administration not reported) via intramuscular route in October 2009. The patient had received a first injection of GARDASIL in August 2009. The patient had been sent to a rheumatologist by her family doctor for intense asthenia and polyarthralgia which began in mid-November 2009. In mid-November, onset of arthralgia in wrists, hands, ankles and knees without joint swelling, without night waking with a period of morning stiffness which lasted approximately one hour. These were isolated symptoms without any other clinical focus. On 14-JAN-2010: sedimentation rate = 46 mm 1st hour, CRP = 21 mg mg/L, fibrinogen = 4.21 g/d, antistreptolysin was negative, rheumatoid factors were negative. On 01-FEB-2010, negative antinuclear antibodies, negative soluble nuclear anti antigen autoantibodies, negative parvovirus serology, sedimentation rate 1st hour = 43 mm, CRP = 11 mg/l, fibrinogen = 4.57 g/l, no anomaly on urinary sediment, negative proteinuria, normal hand radiography, no HLA B27 antigen, negative Lyme disease serology, normal C4 complement. The patient had treatment with ASPIRINE 3 g/d since 15-JAN-2010, which provided partial relief to the patient. She also started treatment with PLAQUENIL on 08-FEB-2010, one tablet daily during one month then two tablets daily. Laboratory values to be checked around 20-MAR-2010 with another consultation with rheumatologist. Outcome to follow. At the time of reporting, the patient had not recovered. To be noted that asthenia and stiffness were added to events coded by health authorities. The health authorities assessed the causal relationship between the reported reactions and vaccination with GARDASIL as 'doubtful' according to the method of assessment. No further information is available.

Other Meds: unknown

Lab Data: diagnostic radiology, 01Feb10, normal hand radiography; serum C-reactive protein, 14Jan10, 21 mg/L; serum rheumatoid factor, 14Jan10, negative; erythrocyte sedimentation rate, 14Jan10, 46 mm; plasma fibrinogen test, 14Jan10, 4.21 g/d; serum

History: unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382756-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Mar-2010	08-Mar-2010	0	16-Mar-2010	16-Mar-2010	AK		21-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2991AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0653X	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3351AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain in extremity, Rash

Symptom Text: Very sore arm-right upper. Redness-rash. Parent applied cold. Gave TYLENOL and patient rested. To school next day.

Other Meds: No

Lab Data: No

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382769-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	24-Feb-2010	25-Feb-2010	1	16-Mar-2010	16-Mar-2010	MI		16-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3438AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion

Symptom Text: patient noted bruising of arm on side of HPV vaccine administration but not directly of site of injection. Bruising lasted 4-5 days

Other Meds:

Lab Data:

History: none of pertinence

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382775-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Aug-2007	12-Oct-2007	51	16-Mar-2010	17-Mar-2010	VA		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Second GARDASIL injection given 8/22/07. Had seizure 10/12/07-followed by Dr. We did not treat or evaluate patient after seizure. Was placed on TOPAMAX.

Other Meds:

Lab Data: Testing done through Dr's office->seizures were determined to be pseudoseizures

History: None known

Prex Illness: None known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382779-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	15-Mar-2010	16-Mar-2010	1	16-Mar-2010	17-Mar-2010	NY		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pyrexia

Symptom Text: Student complained of nausea, dizziness with low grade temperature (100.5)

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382788-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Feb-2010	04-Feb-2010	0	16-Mar-2010	17-Mar-2010	MI		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Headache, Hypoaesthesia, Myalgia, Paraesthesia

Symptom Text: HEADACHES, JOINT PAIN, MUSCLE PAIN, TINGLING AND NUMBNESS IS HANDS AND FINGERS, STOMACH PAIN

Other Meds:

Lab Data:

History: NONE

Prex Illness: SWELLING, REDNESS AND SITE PAIN

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382813-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Mar-2010	15-Mar-2010	0	17-Mar-2010	17-Mar-2010	WI		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain, Paraesthesia

Symptom Text: Upper arm numbness, client states that site has paresthesia and "prickly pain" which occasionally goes into her elbow and hand. Client parent instructed to call primary care physician for follow up.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **382845-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Apr-2009	23-Apr-2009	0	17-Mar-2010	18-Mar-2010	FR	WAES0907USA01036	18-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a health care professional for the pregnancy registry for GARDASIL concerning a 16 year old female patient with no pertinent medical history reported who on 23-APR-2009 was vaccinated with the second dose of GARDASIL (Lot # not reported). It was reported that the patient was pregnant while vaccinated. The last menstrual period dated back to February 2009 and gestation was about 9 weeks. The estimated delivery date was on 08-NOV-2009. At the time of reporting, the patient had no adverse reactions. Follow-up information has been received. The reporter was contacted by telephone. She could not confirm the LMP date but specified that the patient delivered on 20-DEC-2009 by cesarean section and gave birth to a baby girl. The baby had a peripartum infection that kept her hospitalized until 28-DEC-2009 (manufacturer ref. # E2010-01538, WAES# 0907USA01036B1). At the time of reporting, the patient and her baby were well. The event of cesarean section was considered to be an other important medical event. Other business partner numbers include: E2009-05719. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 01Feb09)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382846-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2009	01-Jun-2009	0	17-Mar-2010	18-Mar-2010	FR	WAES1003USA00816	18-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Motor dysfunction, Muscular weakness

Symptom Text: Initial information has been received from a pharmaceutical company physician, concerning a 40 or 41 year old female who on June 2009 (exact date not reported) was administered the second dose of GARDASIL (lot#, batch#, route and site of administration not reported). It was reported that the patient started with clinical picture of motor weakness on July 2009. At the time of reporting the patient continued with this weakness, and she was being studied by the neurology department. The reporter did not know whether the patient was under medical treatment or not. This is a case of misuse. GARDASIL administered to a 40 year old female when this vaccine was indicated for males and females from 9 to 15 years old and females from 16 to 26 years old. The event of muscle weakness was considered to be an other important medical event. Other business partner numbers include E2010-01417. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **382847-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-May-2008	15-Dec-2008	214	17-Mar-2010	18-Mar-2010	FR	WAES1003USA01466	18-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Dyskinesia, Epilepsy, Grimacing, Muscle twitching, Nervous system disorder, Psychomotor hyperactivity, Road traffic accident, Tonic convulsion

Symptom Text: Information was obtained on request by the company from the agency via a public case details form concerning a 21 year old female patient who on 15-MAY-2008 was vaccinated intramuscularly with a second dose of GARDASIL (lot# not reported). It was reported that the patient had epilepsy since childhood, seizure free for 3 years. the patient developed refractory epilepsy around 7 months after the second dose of GARDASIL. In December 2008, the patient had a seizure which resulted in a car crash and subsequently her seizures had been refractory. On 15-DEC-2008 the patient developed epilepsy and was hospitalized. Electroencephalography (EEG) monitoring findings demonstrated the inter-ictal EEG to be markedly abnormal with frequent intermittent paroxysms of high amplitude generalized 3-4 Hz polyspike ad wave activity with a definite right frontal emphasis at times. There were also isolated inter-ictal low amplitude sharp amplitude sharp waves seen at F4 during wakefulness and sleep. Patient was monitored for 48 hours and in that time, ten seizures were recorded of five different types. Four events including left foot pedaling, bilateral upper limb jerks, facial grimacing and right leg twitching all occurred from sleep and were associated with bifrontal/right frontal ictal rhythm. Neuroimaging performed last year demonstrated a small focus of heterotopic grey matter deep within the right frontal lobe. the inter-ictal EEG features of generalized discharges, focal discharges and bursts of generalized paroxysmal fast activity in association with multiple seizures types including tonic seizures and seizures with a right frontal semiology was Highly suggestive of a symptomatic generalized epilepsy. Magnetic resonance imaging (MRI) in January 2009 showed a very small focus of likely heterotopic grey matter in the right oral lobe deep in the grey matter. The patient had tried multiple anticonvulsant KEPPRA and EPILIM, then changed to TOPAMAX and lamotrigine, reduced TOPAMAX to 125 mg/BID and increased lamotrigine to 20 mg mane

Other Meds: Unknown

Lab Data: Electroencephalography, 12Dec08, markedly abnormal; magnetic resonance imaging, ??Jan09, a small focus of heterotopic grey matter deep within the right frontal lobe

History: Absence seizure

Prex Illness: Epilepsy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382848-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Apr-2009	01-May-2009	23	17-Mar-2010	18-Mar-2010	FR	WAES1003USA01648	18-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ2670	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Biopsy site unspecified abnormal, Liver disorder, Pyrexia, Red blood cell sedimentation rate increased

Symptom Text: Initial case was reported on 09-MAR-2010 by the Health Authority (HA reference DK-DKMA-20094710). it was reported that a 16 year old female patient was vaccinated with the second dose GARDASIL (IM lot#NJ2670, batch # NJ34850, site of administration not reported) on 08-APR-2009. It was reported that the patient developed pyrexia, sedimentation rate increased, and Hepatic disease 9 not further specified) on 01-May-2009. it was reported that the patient was hospitalized (date of hospitalization not reported) and the biopsy confirmed the diagnose (not further specified). Outcome was not reported. It was reported that the patient was vaccinated with the first and third dose GARDASIL (IM, batch number and site of administration not reported) on 05-FEB-2009 and 13-AUG-2009, respectively. No adverse reaction or worsening of symptoms were reported. The patient had no concurrent illness and received no concomitant medicine. Other business numbers included E2010-01555. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382863-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Mar-2010	17-Mar-2010	0	17-Mar-2010	17-Mar-2010	TX		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: fainted for appx 20 seconds

Other Meds:

Lab Data: N/A

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **382871-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Mar-2010	17-Mar-2010	0	17-Mar-2010	17-Mar-2010	MI		17-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Hypoaesthesia, Malaise, Pallor, Presyncope

Symptom Text: patient felt "sick," dizzy, and developed numbness in her fingers. this lasted for 30 seconds. she felt as though she was going to "pass out," but she never lost consciousness or vision. she was provided water and orange juice, and she felt better. her systolic blood pressure dropped from 90s to 70s, but went back up to the 90s over an hour or two. pallor, but no rashes. no cough, wheezing, nausea, vomiting, diarrhea, chest pain, or headache.

Other Meds: none

Lab Data: physical exam at 2:00 PM normal.

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **382876-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	23-Apr-2009	23-Apr-2009	0	17-Mar-2010	18-Mar-2010	FR	WAES0907USA01036B1	18-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Neonatal infection

Symptom Text: Information has been received from a healthcare professional concerning a female neonate born via cesarean section who experienced an unspecified peripartum infection. Her mother, a 16 year old female patient, had received the second dose of GARDASIL (batch number not reported) on 23-Apr-2009 (cf linked case). The mother was vaccinated while pregnant. She delivered on 20-DEC-2009. Peripartum infection kept the patient hospitalized until 28 DEC-2009. At the time of reporting, the patient and her mother were well. No further information is expected. Case linked with serious case E2009-05719 (WAES 0907USA01036). Other business partner numbers include E2010-01538. This is a consolidation of two reports concerning the same patient. It was determined that WAES #1003USA01419 was opened without making the split from the mother's episode. Therefore, WAES #1003USA01419 is being deleted from our files and the report had been created from the mother's episode WAES #0907USA01036 and was assigned WAES #0907USA01036B1. WAES #1003USA01419 was previously sent to the FDA on 15-MAR-2010.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **382877-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Nov-2009	12-Dec-2009	28	17-Mar-2010	18-Mar-2010	FR	WAES1003USA01858	18-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1202U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breast abscess, Breast inflammation, Breast pain, Breast swelling, Erythema, Haemorrhagic cyst, Skin warm

Symptom Text: Case received from a physician on 04-MAR-2010: This case was linked with serious case E2009-10795 (WAES # 0911USA04796) (same reporter, same vaccine, similar reactions). A 14 year old female patient had received a second dose of GARDASIL (lot # 1202U, batch # NJ33350) on 14-NOV-2009. Four months after vaccination, the patient went to consultant for pain in breast, and it was observed that the breast was tight, red and warm. Ultrasound showed images in favor of haemorrhagic cyst. A retronipple abscess also occurred at the side of the vaccination. Complete blood count found leukocytes at 8700 and polynuclear neutrophils at 61%. C-reactive protein revealed a little inflammatory syndrome. There was no sign of diabetes. Corrective treatment with AUGMENTIN, 3 g per a day, ibuprofen 3 times 400 mg per a day and acetaminophen were given. Pain and reactions significantly regressed under AUGMENTIN. The check-up showed no adenopathy, skin integrity, no sexual relations and no concept of recent shaving. At the time of the report, the patient had not fully recovered. The reporter considered the case as serious (OPME). To be noted that the patient had received the first dose of GARDASIL in September 2009. She had no history of breast disease in her family. The patient had an abundant menstruation and normally menstruated but was not taken contraception. She had pertussis which had been treated and for which she had been hospitalized late in 2009. Other business partner numbers include E2010-01486.

Other Meds: Unknown

Lab Data: ultrasound, 12?Dec09, haemorrhagic cyst; WBC count, 12?Dec09, 8700, leukocytes at 8700; neutrophil count, 12?Dec09, 61%, polynuclear neutrophils; serum C-reactive protein, 12?Dec09, a little inflammatory syndrome

History: Pertussis

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382905-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	04-Mar-2010	04-Mar-2010	0	17-Mar-2010	18-Mar-2010	MD		18-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1350Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Mass, Pain in extremity, Tenderness

Symptom Text: Received 1st GARDASIL inj 3/4 arm has been sore since, noticed lump 3/9 - tender when trying to exercise pt informed to call Mon and make appt if not better or sooner if nec. 3/12 pt called with numbness in arm instructed to go to ER - seen in ER 3/12 made appt to be seen in office for follow-up 3/12/10 pt called and cancelled appt she made.

Other Meds: seasonique

Lab Data:

History:

Prex Illness: no

Prex Vax Illns:

Vaers Id: **382908-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Mar-2010	17-Mar-2010	1	17-Mar-2010	18-Mar-2010	AR		18-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pain

Symptom Text: Pt complained of headache and body aches.

Other Meds: None

Lab Data: None.

History: None.

Prex Illness: No.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382915-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Sep-2009	Unknown		11-Mar-2010	18-Mar-2010	FL	200904273	18-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0100X	2	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	U2908A	0	Right arm	Intramuscular	
TDAP	UNKNOWN MANUFACTURER	AC52B036BA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Iron deficiency

Symptom Text: Initial report received on 09 October 2009 from a health care professional. A 16 year old female patient, with no medical conditions or allergies, received a right arm 0.5 ml intramuscular injection of MENACTRA (lot number U2908AA) on 16 September 2009 as part as part of routine immunization. The patient was pregnant at the time of vaccination. Concomitant medications included FERROUS SULFATE 325mg. Her last menstrual period was either 15 or 19 August 2009 and her expected date of confinement is 26 May 2010. Prenatal testing was not reported. The patient had no previous pregnancies. No adverse event was reported. The patient had no previous pregnancies. No adverse event was reported. Follow up information received on 28 December 2009 from a health care professional. The patient had a questionable history of high blood pressure and no known use of recreational drugs or alcohol. The patient's last date of her menstrual period was 19 August 2009 and estimated date of delivery was 26 May 2010. In addition to receiving MENACTRA, the patient also received a first dose of Tdap (manufacturer not provided, lot number AC52B036BA) and a third dose of GARDASIL (manufacturer Merck, lot number 0100X) on 16 September 2009. The patient was reported as having an iron deficiency during the pregnancy (onset date not provided) and was being treated with iron. The reporter stated that at the time of the last attempt in contacting the patient, the patient had still not received prenatal care at that time.

Other Meds:

Lab Data:

History: No allergies and no medical history. She had no previous pregnancies. Patient had a questionable history of high blood pressure.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **382921-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Mar-2010	09-Mar-2010	8	18-Mar-2010	18-Mar-2010	MO	MO-2010-05	18-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	12574		Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3058AA		Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3356AA		Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0819Y		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Mobility decreased, Pain in extremity

Symptom Text: After getting shots, client's right arm wa sore for several days and on 3-9-10 was running a temp 100.3 and couldn't raise her arm above shoulder height. Advised to see doctor who gave antibiotics. 3-10-10 no fever and was able to go to school.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **382944-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-Jan-2009	19-Jan-2009	0	18-Mar-2010	19-Mar-2010	MN	WAES0901USA02801	19-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received a Registered Nurse for the pregnancy registry for GARDASIL, concerning a 19 year old female patient with no known allergies and no pertinent medical history, who on 19-JAN-2009 was vaccinated intramuscularly with 0.5 ml of her first and only dose of GARDASIL (Lot# 660391/0063X) while she was pregnant. The urine pregnancy test was positive (LMP: 12-DEC-2008, EED: 18-SEP-2009). As of 15-JAN-2009 the patient was fine. In follow-up the registered nurse reported that they were unable to obtain authorization from the patient. Follow-up information from another registered nurse revealed that the patient has a medical history of Chlamydia infections in September 2007 and January 2009. In February 2009, the patient experienced an elective termination of pregnancy. It was unknown if the fetus was normal or if the products of conception were examined. The patient was seen for LPE (during early-pregnancy) pregnancy test which was positive. The patient did not have obstetric care due to pregnancy terminated per the patient. Upon internal review, elective termination was considered to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: Urine beta-human, positive

History: Chlamydial infection

Prex Illness:

Prex Vax Illns:

Vaers Id: **382945-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-May-2008	01-May-2008	0	18-Mar-2010	19-Mar-2010	FR	WAES1003USA01209	19-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Balance disorder, Dysarthria, Dysgraphia, Fall, Fatigue, Hemiplegia, Hypokinesia, Immune system disorder, Impaired work ability, Insomnia, Loss of consciousness, Malaise, Nausea, Nervous system disorder, Tremor, Vaccine positive rechallenge, Visual acuity reduced

Symptom Text: Information has been received from newspaper articles title via CSL as part of a business agreement concerning a 26 year old female who in May 2008, was vaccinated with the first dose of GARDASIL. Two weeks later, the patient lost her balance and fell. The patient noted that "at the time, she didn't think anything of it. She just thought she was clumsy." In August 2008, the patient received the second dose of GARDASIL. About four weeks after that, all of the symptoms began. The patient lost some of her eyesight, started to feel nauseous, was extremely tired but couldn't sleep. Then she became paralysed on the right side of her body. The patient couldn't walk properly, lack of fine motor skills, and her ability to write went within a week. The patient reported "the whole thing was rapid and slow all the same time. It was like I had had a stroke." The patient sought the help of a neurologist. Between February and July 2009, the patient showed further declined, forcing her to give up her job. The patient noted that "Before all of this she was just so healthy." Since approximately September 2008 (18 months from the time of the article), the patient had been treated for multiple sclerosis and acute disseminated encephalomyelitis, neurological disorders caused by damage to the myelin sheath that covers nerves. It was reported that "the patient's illness remained a mystery and she had not officially been diagnosed with either disease." At the time of article, the patient struggled with paralysis, lack of the fine motor skills, tremors, slurred speech, fatigue, sickness and a compromised immune system. The outcome for lost her balance, fell, lost some of her eyesight, feel nauseous, could not sleep, treated for multiple sclerosis not officially diagnosed, treated for acute disseminated encephalomyelitis not officially diagnosed, neurological disorders, lost ability to write was unknown. The patient also reported that she experienced "blackouts" (onset date, outcome not reported). Upon internal review, lost some of her ey

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 382946-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Sep-2007	18-Sep-2007	0	18-Mar-2010	19-Mar-2010	FR	WAES1003USA01459	19-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Confusional state, Convulsion, Disorientation, Epilepsy, Fatigue, Headache, Pain in extremity, Partial seizures, Somnolence, Tongue biting, Vomiting

Symptom Text: Information was obtained on request by the company from the agency via a public case details form concerning a 16 year old female patient who on 18-SEP-2007 was vaccinated intramuscularly with a dose of GARDASIL (lot not reported). On 18-SEP-2007 the patient developed convulsion and was hospitalized. It was reported that the patient fell asleep on the school bus as she felt a little tired and recalled awakening approximately two hours later being in the back of an ambulance and taken to hospital to the ED. She was apparently disoriented and did not know her name and gave the wrong name and also did not know her parents' names. Apparently she was sitting on the back seat of the bus disoriented and that she had three to four convulsions. She was confused, had a bad headache and vomited twice. She had bitten her tongue, had not been incontinent and the following day her arms and legs were really sore and she slept a lot. CT scan of head was unremarkable and EEG was markedly abnormal demonstrating frequent epileptiform discharges which occurred intermittently in the left frontal region. They were much more marked during sleep and were associated with continual focal low amplitude slowing. It was suspected that the patient had a focal seizure which secondarily generalized a number of times on the bus. Considering it all occurred within the one 24 hours period we called this a single event even though it was apparent that she had a cluster of seizures. The patient was observed in hospital emergency and later she discharged. Subsequent MRI was "unremarkable" and no further seizures within the following 3 months. The patient had been reviewed by a neurologist for 2 times and she was not prescribed anticonvulsants. At the time of this report, the patient had recovered from convulsion. The reporter felt that convulsion was possibly related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Head computed axial tomography, 18?Sep07, unremarkable; electroencephalography, 18?Sep07, markedly abnormal demonstrating frequent epileptiform discharges; magnetic resonance imaging, 18?sep07, unremarkable

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **382947-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	08-Jan-2010	08-Jan-2010	0	18-Mar-2010	19-Mar-2010	FL	WAES1003USA01529	19-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Foetal growth retardation, Intra-uterine death, Uterine dilation and curettage, Vaginal haemorrhage

Symptom Text: Initial and follow-up information has been received from a consumer and medical assistant, for the Pregnancy Registry for GARDASIL. The consumer is a 22 year old female with a history of gallbladder removal about 10 years ago. On 08-Jan-2010, the patient received a dose of GARDASIL (lot # 663454/0672Y) IM. No concomitant vaccinations were administered at that time. The medical assistant stated that on 24-Feb-2010 the patient reported to the physician that she was pregnant. The patient was referred to the obstetrician. Her last menstrual period was on 23-Dec-2009. The consumer reported that she had a urine test when given the vaccine. The test showed she was not pregnant. A few weeks later, she found out she was pregnant. She went in for a blood work and an ultrasound on 06-Mar-2010 (also reported as 07-Mar-2010). They showed she would be 10 weeks pregnant but the fetus stopped growing at 5 weeks. As of 10-Mar-2010, the consumer was also experiencing spotting. The consumer stated that she had visited her physician's office on 11-Mar-2010 and the physician had confirmed that her baby was not properly developing. The consumer also reported that a dilatation and evacuation had been scheduled for her by the physician on 12-Mar-2010. The medical assistant reported that "the patient's sac was measured at six weeks and the patient had a miscarriage". On 12-Mar-2010, the patient was scheduled for a dilatation and evacuation procedure. Upon internal review, the fetus stopped growing at 5 weeks and miscarriage were considered other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 03/06/10, fetus stopped growing at 5 weeks - see narrative; beta-human chorionic, 01/08/10, negative; laboratory test, 03/06/10, fetus stopped growing at 5 weeks - see narrative; beta-human chorionic, 01/??/10, a few weeks later

History: Cholecystectomy

Prex Illness:

Prex Vax Illns:

Vaers Id: **382951-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	01-May-2008		18-Mar-2010	18-Mar-2010	FL		18-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Hypoaesthesia, Immunisation reaction, Pain

Symptom Text: May, 2008 complained of acute severe pain, weakness. (R) leg with numbness. Admitted to local hospital. After seeing numerous MD's, neuromuscular specialist determined due to GARDASIL immunization.

Other Meds:

Lab Data: Complete neurological workup

History: Cataract (congenital); glaucoma

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383065-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Mar-2010	15-Mar-2010	0	19-Mar-2010	19-Mar-2010	MA		19-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3079AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	075Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache, Nausea, Vomiting

Symptom Text: C/O headache, nausea, tired several hours after vaccine administered. Vomited next morning x 1. Lump on (R) side of neck noted on 3/18/10.

Other Meds: None noted

Lab Data: None

History: Allergic to bee stings

Prex Illness: none noted

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383070-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Jan-2010	09-Jan-2010	2	19-Mar-2010	22-Mar-2010	--		23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Computerised tomogram normal, Headache, Lumbar puncture normal, Nuclear magnetic resonance imaging normal

Symptom Text: Daughter got GARDASIL vaccination on 01/07/2010, the second vaccination of the three required, on 01/09/2010, she developed a severe headache and has it to this day. She has not been able to attend school for the past two months and was hospitalized. She has had numerous tests, including two CT scans, a lumbar test, and a MRI; these tests were all negative, yet the headache persists. She has been given strong migraine medicines, one of these took the pain away for two days, but the headache returned after she was released from the hospital. She is still in severe pain and seeing a doctor at least once a week.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383094-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Mar-2010	18-Mar-2010	0	19-Mar-2010	22-Mar-2010	TX		22-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0075Y		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Crying, Dizziness, Feeling cold, Tremor

Symptom Text: Lips trembling, feeling cold with obvious chills, observed kept warm, started feeling dizzy, started crying no difficulty breathing.

Other Meds: None

Lab Data: BP, O2 sats, Temp, VS monitoring

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383095-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Mar-2010	10-Mar-2010	2	19-Mar-2010	22-Mar-2010	OH		22-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C5213046DA	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: Large localized swelling from shoulder to elbow.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **383112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Mar-2010	Unknown		20-Mar-2010	22-Mar-2010	GA		22-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAB359C4	0	Left arm	Unknown	
FLU(H1N1)	UNKNOWN MANUFACTURER	5008491	0	Unknown	Unknown	
HPV4	MERCK & CO. INC.	1318Y	0	Left leg	Intramuscular	
MNQ	SANOFI PASTEUR	U3074AA	0	Right leg	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049CA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1331Y	1	Left leg	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration, Injection site irritation

Symptom Text: Had area of induration and irritation at site of Varicella Vaccination that is improving.

Other Meds: Oral contraception Pills

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383121-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
39.0	F	18-Mar-2010	18-Mar-2010	0	21-Mar-2010	22-Mar-2010	FL		22-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	0	Left arm	Intramuscular	VARCEL
	VARCEL	MERCK & CO. INC.	1113Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Wrong drug administered

Symptom Text: Administered by: MA Symptoms: Inappropriate drug administration; wrong vaccine given to 40 yr. old woman. Injected arm sore for 2days. Injection site sore for four days. 40 yr. old woman was given injectable Merck Gardasil vaccine instead of injectable Merck Varivax vaccine.

Other Meds:

Lab Data: None

History: PCN,any medicine with the -cin ending,Bactrim,Sulfa,Shellfish,PCOS,ITP Syndrome

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383141-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Mar-2010	20-Mar-2010	1	22-Mar-2010	22-Mar-2010	NC		23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318T	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1152Y	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3062AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: RED,SLIGHTLY SWOLLEN AREA ON R ARM SUBCUTANEOUS AREA. KELFEX 500 MG BID X 10 DAYS.

Other Meds:

Lab Data:

History: NO

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **383144-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Mar-2010	19-Mar-2010	0	22-Mar-2010	22-Mar-2010	SD		22-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB343BA	1	Left arm	Unknown	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB818AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	U3040CA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0229X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness

Symptom Text: Pt was ready to go and mom was signing some papers and pt fell forward. I caught her lowered her to ground and she had a small 10 sec seizure. Mom said she has hx of them. Pt woke and asked what happened. Pt was checked by doctor and left. Follow up with pt 3/22/10. Pt doing fine.

Other Meds:

Lab Data:

History: febrile seizures

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383147-1** **Related reports:** 383147-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Mar-2010	16-Mar-2010	0	22-Mar-2010	22-Mar-2010	MD		22-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TD	SANOFI PASTEUR	C3352AA	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	13184	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	63010AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Cyanosis, Eye disorder, Fall, Headache, Loss of consciousness, Musculoskeletal stiffness, Pain, Skin discolouration, Tongue disorder, Urinary incontinence

Symptom Text: Less than 5 minutes after receiving vaccines patient passed out on the bed, fell down from the bed to floor and became unconscious, stiff, fingers and hand turned outward, face turned white and blue, eyes rolled back, tounge was sticking out and she became completely soaked in urine. I (parent) screamed and called for help. Head was stuck under wooden board found at the bottom of examining table and her head had to be pulled out. About 5 minutes later came around, put hands on head, seemed unaware of what had occurred. Blood pressure was taken after that. She was observed and sent home. For next 2 days had headache and body was weak and sore.

Other Meds: triamcinolone on hands for dry skin

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383147-2** **Related reports:** 383147-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Mar-2010	16-Mar-2010	0	26-Mar-2010	26-Mar-2010	MD		26-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3352AA	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3010AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Tonic convulsion

Symptom Text: Had syncope and what seems to be 30 sec tonic seizure. Awoke and spoke appropriately with us before allowing her to leave after observation period.

Other Meds: Triamcinolone cream

Lab Data: Sent to neurology

History: Eczema

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383161-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Feb-2010	25-Feb-2010	0	22-Mar-2010	23-Mar-2010	--	201001565	23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3352AA		Right leg	Unknown	
	MNQ	SANOFI PASTEUR	43080AA		Left leg	Unknown	
	HPV4	MERCK & CO. INC.	1317Y		Left leg	Unknown	
	HEPA	MERCK & CO. INC.	1538Y		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Paraesthesia, Urticaria

Symptom Text: Initial report was received on 16 March 2010 from another manufacturer, with document number WAES 1003USA00893. The initial reporter to this manufacturer was a healthcare professional. Verbatim from the report: "Information has been received from a physician and licensed practical nurse. Information concerning a 14 year old female with attention deficit disorder and allergic to Penicillin who on 25-Feb-2009 was IM vaccinated with a first dose of GARDASIL vaccinated on 25-Feb-2010 with a dose of GARDASIL (Lot no. 662529/1317Y) given in left upper thigh; a dose of VAQTA (Lot no. 666201/1538Y) given in right upper thigh; a dose of MENACTRA (Lot # 430800AA) given in left lower thigh and a dose of ADACEL (Lot # C3352AA) given in right lower thigh. Concomitant medication included ADDERALL." "It was reported that the patient called the physician's office at the afternoon, the patient experienced hives, nausea and dizziness and also complaint of tingling in both legs. Patient had taken 12.5 mg. of BENADRYL twice before going to the emergency room. The patient was seen at approximately 23:00PM the same day and symptoms were gone. Patient received a dose of SOLU MEDROL IV and ZANTAC prior to being discharged from emergency room. At the time of the report the patient was recovered." "Upon internal review, hives, nausea, dizziness and tingling in both legs were considered to be other important medical events." "No further information is available." Of note, MENACTRA lot number 43080AA (also reported as 430800AA) is not a valid sanofi pasteur lot number. Documents held by sender: None.

Other Meds: ADDERALL

Lab Data:

History: The patient's medical history included attention deficit disorder and a penicillin allergy. It was not reported if the patient had any illness at the time of the vaccinations.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383166-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Mar-2010	Unknown		22-Mar-2010	22-Mar-2010	TN		22-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1446Y	2	Unknown	Subcutaneously	
HPV4	MERCK & CO. INC.	0672Y	2	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	C3079AA	1	Unknown	Intramuscular	
TDAP	SANOFI PASTEUR	C3353AA	1	Unknown	Intramuscular	
HEPA	MERCK & CO. INC.	1397Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: On 3/11/10 pt. received 3 vaccines that were not needed. She had already had them. The PHOA failed to print out the immunization screen from PTB MIS, so the nurse did not know she had already had them. Called and spoke with house parent - no side effects noted, no problems.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383167-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Mar-2010	15-Mar-2010	3	22-Mar-2010	22-Mar-2010	NE		22-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash maculo-papular

Symptom Text: Received HPV 3-12-10 @ 1600 L delt. Noted macular papular rash after noon 3-15-10 on L delt. Pt instructed by PAC to take ZYRTEC 10 mg once daily.

Other Meds: MINOCIN 100 mg BID

Lab Data:

History: CECLOR; BACTRIM; SEPTRA

Prex Illness: none

Prex Vax Illns:

Vaers Id: **383172-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Jan-2009	29-Jan-2010	366	22-Mar-2010	23-Mar-2010	FR	WAES1002USA02945	23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1882U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Drug intolerance, Headache, Hypokinesia, Injection site pain, Injection site swelling, Myalgia, No reaction on previous exposure to drug, Pyrexia

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 28-JAN-2009 around 5 p.m., was vaccinated with a second dose of GARDASIL vaccine (route not reported, lot number 1882U, batch number NJ08320). In the night, around half past midnight, on 29-JAN-2010, the patient experienced very intense headache, violent pains at the level of the abdomen, very intense muscle pain, with difficulty moving and fever at 39 degrees C. All events were reported as severe. The patient took corrective treatment with DOLIPRANE, and timebutine. The next morning at 9a.m., the patient's condition had improved with regression of muscle pain and fever, in spite of persisting headache and abdominal pain of lower intensity. It was noted that the patient received the first dose of GARDASIL vaccine one and a half months before this report (on approximately 14-DEC-2009). Additional information was received on 29-JAN-2010. The physician specified that the vaccine had been stored at the patient's home at a temperature of 5C. Additional information was received on 10-FEB-2010. The physician provided the patient's initials. She also reported that "everything had gone back to normal" 2 days after vaccination, and that the patient had not experienced adverse events after the first dose of GARDASIL vaccine. Follow-up information was received on 17-MAR-2010. Upon medical review, the case was upgraded to serious according to the reporter's assessment. The patient's initials were corrected. Her date of birth, weight and height were provided. The patient was 16 years old at the time of the events and not 17 as initially mentioned. The patient had no personal medical history. She received the injection of GARDASIL vaccine intramuscularly into the left arm. 6 hours after vaccination, she experienced cephalgia, fever at 39C, violent myalgia and abdominal pain. Six and a half hours after vaccination, the patient experienced swelling and pain at the injection site. Cephalgia and myalgia were described as "very violent". The repor

Other Meds: Unknown

Lab Data: Body temp, 29Jan10, 39 C

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383173-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Mar-2010	23-Mar-2010	--	WAES1003USA02406	23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Human papilloma virus test positive, Menstrual disorder, Papilloma viral infection, Precancerous cells present

Symptom Text: Information has been received via the internet from a consumer concerning his or her daughter who was vaccinated with 2 doses of GARDASIL (lot number, date, route and site not reported). Approximately a year later the patient had tested positive for high-risk HPV. The patient suffered SEVERE side effects from them which incapacitated her for 2 1/2 months. The patient continued to experience menstrual problems even though it had been over a year. At the time of the report, the patient had precancerous, high-risk HPV. It was reported that the reporter believe that the patient's HPV was the result of the vaccines because the patient did not have HPV when she received the vaccines. Severe side effects and menstrual problems were considered to be disabling. This is one of several reports received from the same source. Attempts to verify the existence of an identifiable patient have been unsuccessful.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383175-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		22-Mar-2010	23-Mar-2010	--	WAES1003USA02519	23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a consumer via an internet newspaper concerning a patient who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that a parent can be guilty because if he had known about the side effects, then he might not have allowed the pediatrician to vaccinate the child, which resulted in death (cause of death unspecified). It was unknown if the patient sought medical attention. It was also reported that polysorbato 80 or tween 80 that is a chemical that causes infertility in mice and aluminum which is neurological toxin are in GARDASIL. This is one of several reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383262-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Mar-2010	22-Mar-2010	0	22-Mar-2010	23-Mar-2010	KS		23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500849P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0249Y	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3351AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF544AA	5	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3061AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Skin discolouration, Syncope

Symptom Text: Patient recieved five vaccines at time of visit. After receiving her vaccines she stated that she felt weak and then she fainted. The patient had not eaten. After the patient came to, she was given juice and pretzels. We kept her until she was feeling better and regained color in her face.

Other Meds:

Lab Data: N/A

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383264-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Mar-2010	22-Mar-2010	0	22-Mar-2010	23-Mar-2010	OK		23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0075Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF544AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3076AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Petechiae

Symptom Text: Within 15 minutes of administration Meningococcal vaccine patient exhibited scant generalized petechiael less than 1 mm in diameter on left arm between wrist and deltoid muscle. No respiratory distress or evidence of petechiae on abdomen, or other extremities. No other untoward signs noted. Home with Mother, if develops any other stymptoms to take to PP or ED. @ 3:00 pm phone call to Mother, "no change in petechiae, no other problems @ this time. Will follow-up 3/23/10.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 383270-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Feb-2010	11-Feb-2010	2	22-Mar-2010	23-Mar-2010	VT		23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Endotracheal intubation, Grand mal convulsion, Postictal state, Sedation, Simple partial seizures

Symptom Text: 30-45 minute simple partial seizures followed by grand mal at about 7:00 pm. Very challenging post-ictal state requiring sedation and intubation, and 2 day hospital stay. Second seizure on 2/27/2010 followed same pattern. following

Other Meds:

Lab Data: Epilepsy- no cause determined; lingering language and motor difficulties. MRI, CT, EEG and all labs were good.

History: allery to Keflex- reaction is hives; no other mediccal conditions

Prex Illness: mild cold symptoms

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383290-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	10-Feb-2010	10-Feb-2010	0	23-Mar-2010	23-Mar-2010	NE		23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3045AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1099Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Flushing, Injection site erythema, Pyrexia, Rash macular

Symptom Text: Pt lightheaded after receiving MENACTRA R D and GARDASIL L Deltoid. Pt became flushed and developed red flat blotches on face and neck which resolved approximately 15 minutes about 2 x 4 inch raised erythematous area developed at site of MENACTRA injection (R deltoid). BENADRYL given and BP's monitored. No difficulty with breathing. T=99.7 Rechecked=99.0 BP 104/50 (71).

Other Meds:

Lab Data:

History: Allergic to penicillin

Prex Illness:

Prex Vax Illns:

Vaers Id: 383291-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Aug-2008	13-Sep-2008	18	23-Mar-2010	24-Mar-2010	--	WAES1003USA01956	24-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0512X		Unknown	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52Z015AA		Unknown	Unknown	
MNQ	SANOFI PASTEUR	U2429AA		Unknown	Unknown	
HPV4	MERCK & CO. INC.	0523U		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Chronic fatigue syndrome, Condition aggravated, Depression, Migraine, Syncope

Symptom Text: Initial and follow up information has been received from a office medical assistant concerning her 12 year old daughter with no known drug allergies, neurocardio syncope since the 5th grade, Helicobacter pylori, irritable bowel syndrome and asthma who on 26-AUG-2008 (also reported 13-AUG-2010) was vaccinated with a dose of GARDASIL (Lot#657868/0523U) and VARIVAX (Oka/Merck) (Lot#660944/0512X) at a county health. Concomitant vaccination included MENACTRA and BOOSTRIX. Other concomitant therapy included FLORINEF, TOPAMAX and PREVACID. On 13-SEP-2008 the patient experienced chronic fatigue syndrome. Then the patient's neurocardio syncope was exacerbated leading to migraine headaches and was hospitalized twice in 2008, for an unspecified amount of time. On an unspecified date, the patient was seen by psych who said that the patient was depressed and brought on her own headaches. The reporter stated that this was not true. The patient had been followed by neurology for her neurocardio syncope. It was noted that the patient has been home schooled since 2009, since her conditions keep her from going to school. At the time of the report, the patient had not recovered. Therapy with GARDASIL was discontinued. Chronic fatigue syndrome, exacerbated neurocardio syncope, migraine headaches and depressed were considered to be disabling by the office medical assistant. Additional information has been requested.

Other Meds: FLORINEF; PREVACID; TOPAMAX

Lab Data: Unknown

History:

Prex Illness: Neurocardiogenic syncope; Helicobacter pylori infection; Irritable bowel syndrome; Asthma; Prophylaxis

Prex Vax Illns:

Vaers Id: **383292-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Oct-2007	07-Nov-2007	12	23-Mar-2010	24-Mar-2010	FR	WAES1003USA01399	24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Urticaria, Vaccine positive rechallenge

Symptom Text: Information has been received from a Health Authority (reference number PEI2010003888). It was reported by a physician that an 18 year old female patient was vaccinated with a second dose of GARDASIL (lot number, injection site and route not reported) on 28-DEC-2007. Subsequently the patient experienced aggravation of urticaria which had begun on 07-NOV-2007 after the first dose of GARDASIL given on 26-OCT-2007. Up to time of reporting to Health Authority urticaria was recurring and patient had not recovered. The third dose was not given. Upon internal review the case was considered as serious due to medical judgement. Other business partner numbers include E2010-01494. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383300-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.2	M	17-Sep-2009	17-Sep-2009	0	23-Mar-2010	23-Mar-2010	VA		23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	IPV	SANOFI PASTEUR	D0052	0	Right leg	Unknown	
	DTAP	SANOFI PASTEUR	C3142AA	0	Left leg	Unknown	
	HIBV	SANOFI PASTEUR	UF599AA	0	Left leg	Unknown	
	HPV4	MERCK & CO. INC.	0659Y	1	Right leg	Unknown	
	PNC7	WYETH PHARMACEUTICALS, INC	D63486	0	Left leg	Unknown	
	ROTHB5	MERCK & CO. INC.	0147Y	0	Unknown	By Mouth	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Irritability

Symptom Text: Excessive fussiness and crying over 4 hours.

Other Meds: None

Lab Data: None

History: Benign neonatal seizure on 7/16/09.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **383301-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	28-Dec-2009	28-Dec-2009	0	23-Mar-2010	24-Mar-2010	FR	WAES1003USA02298	24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyskinesia, Eye rolling, Hypotension, No reaction on previous exposure to drug, Syncope, Tonic clonic movements

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail form concerning a 21 year old female patient who on 28-DEC-2009 was vaccinated with the third dose of GARDASIL (intramuscular route, lot # unknown). On 28-DEC-2009, the patient collapsed shortly after receiving the third dose of GARDASIL, her body had 2-3 jerks and her eyes rolled upward. It was reported that the episode lasted less than 1 minute. It was reported that the blood pressure was low post episode so the general practitioner insisted on IV line and transferred the patient to the hospital. It was reported that the patient did not have problems following the first and second dose of GARDASIL. The agency felt that hypotension and tonic clonic movements were possibly related to therapy with GARDASIL. On 28-DEC-2009, the patient recovered. The original reporting source was not provided. Additional Information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **383302-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2009	01-Jun-2009	31	23-Mar-2010	24-Mar-2010	NY	WAES0907USA05002	24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy Registry product, concerning a female patient with no pertinent medical history and no known allergies who in March 2009, was vaccinated IM with the first 0.5 ml "standard dose" of GARDASIL (lot number not reported). In May 2009 the patient was vaccinated IM with the second 0.5 ml "standard dose" of GARDASIL (lot number not reported). There was no concomitant medication. Subsequently the patient became pregnant. The last menstrual period (LMP) was 01-JUN-2009. A home pregnancy test was performed. The physician saw the patient on an unspecified date. The patient's outcome was not reported. Follow-up information has been received from the physician reported that the patient decided to terminate her pregnancy in the first trimester of 2010. Upon internal review, abortion was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 6/1/2009)

Prex Vax Illns:

Vaers Id: **383303-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Mar-2010	Unknown		23-Mar-2010	24-Mar-2010	FR	WAES1003USA02785	24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Pain, Pain in extremity

Symptom Text: Information has been received from a consumer via a health authority as part of a business agreement (manufacturer control # 20100317KC2) concerning her niece, a 13 year old female patient who on approximately 07-MAR-2010, "one and a half weeks ago" was vaccinated with a dose GARDASIL and a dose of RECOMBIVAX HB (manufacturer unspecified). Several days later, the patient developed severe arm pain in both arms. This settled a little with the use of pain killers including PANADEINE FORTE. Pain intensity then increased and the patient was admitted to a hospital. The patient had been on inpatient at the hospital for the last 3 days. At the time of the report, the patient had not recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **383308-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	09-Feb-2010	10-Feb-2010	1	23-Mar-2010	24-Mar-2010	FR	WAES1003USA02326	24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Lymphopenia, Myalgia, Pyrexia, Tachycardia

Symptom Text: Information has been received from the agency via a Case Line Listing via CSL, as part of a business agreement, concerning a 19 year old female who on 09-FEB-2010 was vaccinated IM with a 0.5 mL third dose of GARDASIL (batch # reported as NJ44150, valid for COZAAR). On 10-FEB-2010, less than 24 hours post vaccination, the patient experienced headache (not severe), myalgia (not severe), tachycardia (severe), fever (not severe) and lymphopenia (severe) and was hospitalized. Subsequently, the patient recovered without sequelae from headache (not severe), myalgia (not severe), tachycardia (severe), fever (not severe) and lymphopenia (severe). The reporter felt that headache (not severe, myalgia (not severe), tachycardia (severe), fever (not severe) and lymphopenia (severe) were possibly related to therapy with GARDASIL. No further information was available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383311-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	12-Mar-2010	14-Mar-2010	2	23-Mar-2010	23-Mar-2010	PA		23-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3356AA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3058AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Rash, Rash erythematous

Symptom Text: 2" erythematous rolling patches with central clearing, warm non tender no indurations. BL deltoid.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **383350-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Jul-2009	29-Jul-2009	20	23-Mar-2010	23-Mar-2010	MT		24-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	UF471AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2914AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	ALTAVB350AA	0	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Autoimmune disorder, Hypoaesthesia, Juvenile arthritis, Sensory loss

Symptom Text: My daughter received her vaccination and in August she started showing symptoms. Her limbs were becoming numb. She was loosing feeling in different parts of her body. At the end of August, she was diagnosed with the auto-immune disease Juvenile Rheumatoid Arthritis.

Other Meds:

Lab Data: We took blood tests and were sent to the Hospital. They ran blood tests, took bone scans, took x-rays, etc.

History: no

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383392-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Feb-2010	26-Feb-2010	2	23-Mar-2010	24-Mar-2010	IN		24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Vision blurred

Symptom Text: Pt mom states patient woke up 2 days after HPV#2 vaccination with a headache, dizziness, blurred vision. States mom took child to walk in clinic to see doctor and was given meclizine prescription.

Other Meds: none

Lab Data: none done @ walk in clinic

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **383396-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Dec-2009	15-Jan-2010	28	23-Mar-2010	24-Mar-2010	IL		24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	3	Left arm	Intramuscular	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500835P	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling abnormal, Staring, Tunnel vision

Symptom Text: States started as "deja-vu" like feeling, tunnel vision and progressed to blank stare. Last 30 secs to 2 minutes, now with increasing frequency. Seen in Er with negative head Ct on 02/27/2010 and referred to neurology. Seen by neurology with abnormal EEG and started on Keppra.

Other Meds:

Lab Data: normal head ct, abnormal EEG.

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383420-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Mar-2010	17-Mar-2010	0	24-Mar-2010	24-Mar-2010	TX		24-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia

Symptom Text: Vaccine administered on 3/17/2010 in left arm. The same evening, began experiencing muscular pain in left quadriceps muscles only- no pain on hamstrings or calf muscles- no other neurological signs, no pain elsewhere. Resolved over 48 hours.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **383427-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	15-Jan-2009	26-Jan-2009	11	24-Mar-2010	25-Mar-2010	FR	WAES0902COL00003	25-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0719X		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Areflexia, Asthenia, Ataxia, Autonomic nervous system imbalance, Balance disorder, Bradycardia, Dizziness, Epistaxis, Feeling cold, Fluid intake reduced, Flushing, Guillain-Barre syndrome, Headache, Hyporeflexia, Immunoglobulin therapy, Leukocytosis, Muscle atrophy, Muscle contractions involuntary, Muscular weakness, Polyneuropathy, Pyrexia, Somnolence, Tachycardia, Tremor, Vertigo, Vomiting

Symptom Text: Information has been received from a physician concerning a 10 year old female with a history of drug intolerance to UNASYN, unilateral small kidney and vesicoureteric reflux who on 15-JAN-2009 was vaccinated with GARDASIL (lot # 0719X), there was no concomitant therapy and there was no preexisting illness. On 26-JAN-2009 the patient experienced cephalea, dizziness, vomiting and febricula and was hospitalized to receive intravenous fluids since she was intolerance to oral fluids. On 27-JAN-2009 the patient recovered from the event of febricula. Subsequently patient recovered from cephalea and vomiting. The patient was released from the hospital 1 day later. On 30-JAN-2009 the patient persisted with the symptoms, was evaluated by a neurologist who at physical exam finds general tremor, ataxia and loss of balance. Was hospitalized again and received treatment with dexametasone. On 31 Jan 2009 the patient presented loss of distal strength. The nerve conduction study reported a polyneuropathy compatible with Guillain Barre Syndrome. The patient presented signs of autonomic dysfunction given by facial flushing and coldness. She was treated with gamma globulin. The patient's Guillain Barre Syndrome persisted. The reporter felt that the cephalea, dizziness, vomiting, Guillain Barre Syndrome and febricula were related to therapy with GARDASIL. On 5-Feb-2009 the physician reported that until 4 Feb 2009 the loss of strength in extremities had progressed and the reflexes disappeared. The pulmonary capacity maintained preserves, the patient had not present autonomic dysfunction anymore, and there had not been sensibility or cranial nerves compromise. The patient had always been aware. From 4-Feb-2009 the patient started to recover the strength until 45 grades in lower limbs, better distal strength in lower and upper limbs, and her reflexes reappeared. On 6-Feb-2009 the physician reported the patient presented on 5-Feb-2009 with signs of autonomic dysfunction given by transient dizziness, tachycardia and bradycardia. The pati

Other Meds: unknown

Lab Data: Computed axial tomography, ??Feb08, normal; spinal tap, 30Jan09, normal; magnetic resonance imaging, 30Jan09, normal; hearing test, 30Jan09, normal; nerve conduction study, 31?Jan09, polyneuropathy, compatible with Guillain-Barre Syndrome;

History: drug intolerance; unilateral small kidney; vesicoureteric reflux

Prex Illness:

Prex Vax Illns:

Vaers Id: **383428-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Feb-2009	01-Feb-2009	0	24-Mar-2010	25-Mar-2010	FR	WAES1001USA00107	25-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Chlamydia test negative, Pelvic inflammatory disease, Pneumoperitoneum, Uterine disorder

Symptom Text: Information has been received from a gynecologist concerning a female who on an unspecified date was vaccinated with her first dose of GARDASIL. The patient had been laparoscoped by the reporter and presented with persistent abdominal pain coming shortly after the vaccination. The laparoscopy revealed widespread Pelvic Inflammatory Disease. Her right tube and ovary completely buried in adhesions and she had severe uterine serosal adhesions. Cervical STD swabs had returned negative. At the time of the report, the outcome was not provided. In follow-up, the gynecologist indicated that in August 2008, November 2008 and February 2009, the 19 year old patient received the first, the second and the third doses of GARDASIL (lot # not reported) respectively. It was reported that the patient experienced abdominal pain shortly after the third dose of GARDASIL. An ultrasound in September 2009 revealed free fluid in pelvis; containing septations and internal echoes consistent with pelvic inflammatory disease. On 18-NOV-2009, the patient was diagnosed with PID and was hospitalized. On 18-NOV-2009, a diagnostic laparoscopy revealed widespread filmy adhesions from anterior uterine fundus to bladder and lower pelvic wall peritoneum. Distal end of right tube completely buried with ovary along the right pelvic wall. Further filmy adhesions in Pouch of Douglas from uterus to posterior peritoneal wall. A band adhesion from proximal end of left tube to pelvic wall otherwise left tube and ovary looked relatively unscathed with healthy appearing fimbria and a healthy appearing ovary. The patient developed a Litre pneumoperitoneum. Satisfactory view were obtained via camera. Fluid was aspirated from Pouch of Douglas and forwarded from microbiology including Chlamydia. STD, cervical and high vaginal swabs taken. Vicryl Rapide to suprapubic and subumbilical incisions following peri-incisional Marcaine infiltration was done. The cervical swabs were negative for chlamydia and the patient was in monogynous sexual relationship. The reporting

Other Meds: Unknown

Lab Data: ultrasound, ?? Sep 09, consistent with PID; laparoscopy, 18 Nov 09, revealed widespread pelvic inflammatory disease, see narrative; cervical smear, 18 Nov 09, cervical STD swabs negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **383429-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Mar-2010	25-Mar-2010	--	WAES1003USA02415	25-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autism, Condition aggravated

Symptom Text: Information has been received from an article on the internet concerning GARDASIL. It was reported that "GARDASIL gave the silent faces of autism a voice". The internet article reported that "many parents of autistic children who regressed after vaccination episode, the mild, moderate, and supposedly "rare" side effects of vaccinations resemble post-vaccinal symptoms manifested by their child." At the time of this report, the patients' outcomes were unknown. Attempts to verify the existence of an identifiable patient have been unsuccessful. Upon internal review, worsening autism was considered to be an other important event. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Autism

Prex Vax Illns:

Vaers Id: 383436-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Feb-2010	17-Mar-2010	19	24-Mar-2010	24-Mar-2010	--		25-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Contusion, Convulsion, Eye injury, Face injury, Fatigue, Muscle spasms, Urinary incontinence

Symptom Text: First dose of GARDASIL was received on 12/22/09. No known side effects. Second dose received on 02/26/10. On 03/17/10, my daughter stated she was very tired after eating dinner. She went to the couch to take a nap. Approximately 20 minutes later, she was found on the floor with severe trauma to her face. Urine was on the couch, but more was on the floor where she was found. Although nobody witnessed the event, we all believe she had a seizure. There is no family history of seizures. She has suffered severe injuries to her left eye, large knot over her left eye, and bruising over her entire face, under her chin and behind her ears. She was immediately taken to the ER by ambulance. While in the ER, she complained of her legs spasming. Numerous tests were done, all of which-blood work, EKG, CT scan-came back fine. Today, 3 days after this event, my daughter is still very tired. My daughter is a perfectly healthy, active child who has never had any medical problems until now. After reading numerous reports from other parents who had their child receive GARDASIL, I am convinced this must be the culprit. Nothing else has changed in her life besides receiving this shot.

Other Meds:

Lab Data: All blood work, cat scans, EKG, etc have to date come back normal. No drugs or alcohol in her system the night of the event. Appointment with neurologist has been set for Wednesday, March 24, 2010.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **383486-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	30-Sep-2009	30-Sep-2009	0	25-Mar-2010	25-Mar-2010	VA		25-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Rash macular

Symptom Text: Within 20min of vaccine, developed large red blotches over arms and trunk.

Other Meds:

Lab Data:

History: Allergic rhinitis

Prex Illness:

Prex Vax Illns:

Vaers Id: **383499-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
34.0	F	01-Feb-2010	01-Feb-2010	0	25-Mar-2010	26-Mar-2010	FR	WAES1003SGP00015	26-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Rash

Symptom Text: Information has been received from a physician who learnt from his colleague that a 34 year old female with acne who in February 2010, was vaccinated with her first dose of GARDASIL. Concomitant therapy included sulfamethoxazole/trimethoprim. 3 days after her first dose, the patient experienced rash on her face and upper body. She saw a doctor for her rash and got better but subsequently her rash worsened and she was hospitalized. She was reviewed by the dermatologist who commented that the rash may be due to allergy to GARDASIL or sulfamethoxazole/trimethoprim. The final conclusion from dermatology was that the rash is due to allergy to GARDASIL. Further information will be provided once available.

Other Meds: Sulfamethoxazole/trimethoprim

Lab Data: Unknown

History:

Prex Illness: Acne

Prex Vax Illns:

Vaers Id: **383500-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-Mar-2010	15-Mar-2010	0	25-Mar-2010	26-Mar-2010	IN	WAES1003USA02508	26-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a medical assistant concerning a 21 year old female patient with sulfonamide allergy, and no pertinent medical history, who on 13-JAN-2010, was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (lot number not reported). There was no concomitant medication. On 15-MAR-2010, the patient received intramuscularly the second 0.5 mL dose of GARDASIL (lot number not reported). On 15-MAR-2010, immediately after receiving the second dose, the patient "fainted and had a seizure". The patient was referred to the Emergency Room for evaluation. Computerized tomography of head performed on 15-MAR-2010 was negative. It was not known if the patient was admitted to the hospital. The patient's outcome was unknown at the time of reporting. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Head computed axial, 03/15/10, negative

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383584-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Mar-2010	17-Mar-2010	0	26-Mar-2010	26-Mar-2010	GA		26-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB359BA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1099Y	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt. fainted

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383585-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Mar-2010	11-Mar-2010	0	26-Mar-2010	26-Mar-2010	GA		29-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt fainted

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383591-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Aug-2009	01-Sep-2009	31	26-Mar-2010	26-Mar-2010	CT		29-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin wrinkling

Symptom Text: Seeing patient for aquaogenic wrinkling of the palms. By history patient 1st noted after 1st GARDASIL vaccine. It was improving by history then worsened after her booster about 6 months later.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **383663-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	24-Mar-2010	24-Mar-2010	0	26-Mar-2010	29-Mar-2010	NM		29-Mar-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3060AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037AA	0	Right arm	Intramuscular	
FLU	SANOFI PASTEUR	U3232AA	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1013Y	0	Left arm	Intramuscular	
FLU(H1N1)	UNKNOWN MANUFACTURER	UP053AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope approximately three minutes after injections. Pt. placed supine with lower extremities elevated; instant return of skin color to pink and conscienceness. BP - 98/70 pulse 78 O2 SaO2 - 95 %. Vitals rechecked at five minutes. BP - 104/68 pulse 86 SaO2 97%.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: 05/30/2008~Varicella (no brand name)~2~10.00~Patient|05/30/2008~Hep A (no brand name)~2~10.00~Patient

Vaers Id: **383689-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Jun-2008	01-Nov-2008	136	28-Mar-2010	29-Mar-2010	IL		29-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Activities of daily living impaired, Anxiety, Chest discomfort, Dizziness, Eye pain, Fatigue, Muscular weakness, Myalgia, Nausea, Palpitations, Panic attack, Paraesthesia, Suicidal ideation

Symptom Text: heart pounds, chest tightness, dizzyness, nausea. I thought I was having panic attacks. experienced extreme fatigue and muscle weakness. Hospitalized 9/15/2009 because I was suicidal because I grew tired of living this way. I was put on an anti-depressant (Lexapro), which has helped a little with anxiety (which I never had until after Garadasil adverse side effects). It is now 3/28/10, and I experience tingling sensation in my legs almost constantly and sometimes in my lower arms. My chest is tight, and my muscles ache. I still have symptoms that feel like panic attacks, but the worst would be the fatigue. My eyes hurt, and pre-med major is difficult when so exhausted (let's not forget the difficulty of working full-time as well, as I am an independent student). Since Gardasil, my life has become hell at a time when I should be in my prime.

Other Meds: None before Gardasil. After Gardasil, tried tranquilizer..didn't help. Following hospitalization, on Lexapro and currently switching to Paxil (minor anxiety relief).

Lab Data: Lab tests in hospital came back "normal," but so have numerous other girls who suffer the same condition.

History: None.

Prex Illness: None.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 16-MAY-09 - 30-MAR-10 All comb. w/AND

Vaers Id: **383701-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	25-Mar-2010	26-Mar-2010	1	29-Mar-2010	29-Mar-2010	OK		29-Mar-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1006Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site mass

Symptom Text: 2 " red lump right upper arm

Other Meds:

Lab Data:

History:

Prex Illness: none

Prex Vax Illns:

Total Non Serious	**1973**	**75%**
Total Serious Non Fatal	**622**	**24%**
Total Death:	**25**	**1%**
Total All Reports:	**2620**	

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **274594-2** **Related reports:** 274594-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Feb-2007	17-Feb-2007	0	16-Jun-2010	16-Jun-2010	CA	WAES0702USA01952	17-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug hypersensitivity, Influenza like illness

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter with and Arrithromycin allergy who on 15-JAN-2007 was vaccinated with the first dose of GARDASIL and on 17-FEB-2007 was vaccinated with the second dose of GARDASIL. On 17-FEB-2007 the patient experienced flu like symptoms that only lasted a few days. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **274705-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Feb-2007	16-Feb-2007	0	16-Mar-2007	02-Apr-2007	KY	WAES0702USA04332	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1280F	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0167U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Injection site erythema, Oedema peripheral

Symptom Text: Information has been received from a health professional ("nurse"), via a company representative concerning a 15 year old female who on approximately 14 Feb 2007 ("sometime last week") was vaccinated IM with a second dose of Gardasil vaccine (yeast) (the patient's first vaccination date was not reported). Concomitant suspect vaccinations included a dose of Varicella and hepatitis A vaccine (inactive). On approximately 14 Feb 2006 ("sometime last week"), the instant after getting the vaccinations, the patient developed a "swallowed" red arm 8-9cm long and 6 cm wide. At the time of the report, it was unknown if the patient had recovered. The patient sought unspecified medical attention. Additional information has been requested. This is in follow-up to report (s) previously submitted on 3/14/2007. Information has been received from a health professional ("nurse"), via a company representative and a physician concerning a 15 year old female (weight 124.25%, height 66.5%) with codeine and sulfa allergies who on 16-FEB-2007 was vaccinated IM in the left arm with a second dose of GARDASIL (lot #656049/0187U) (the patient's first vaccination date was not reported). Concomitant suspect vaccinations on 16-FEB-2007 included the second dose of VARIVAX (lot # 654757/1257F), SC in the left arm and the first dose of VAQTA (lot #656017/1280F), IM in the right arm. Other concomitant medication was not reported. On 16-FEB-2006, the instant after getting the vaccinations, the patient developed a "swallowed" red arm 8-9 cm long and 6 cm wide (also reported as redness at the sie of the injection). The patient sought unspecified medical attention and was treated with ZYRTEC. On 16-FEB-2007, the patient recovered from the event. Additional information is not expected. This is in follow-up to report (s) previously submitted on 3/14/2007; 7/6/2007. Information has been received from a health professional ("nurse"), via a company representative and a physician concerning a 15 year old female with codeine and sulfa allergies who on 16-F

Other Meds: Unknown

Lab Data: Unknown

History: Immunization

Prex Illness: Drug hypersensitivity; Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **292091-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
36.0	F	26-Mar-2007	26-Mar-2007	0	20-Sep-2007	12-Mar-2008	MN	WAES0708USA01595	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0014U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Medication error, Rash, Wrong drug administered

Symptom Text: Information has been received from a licensed practical nurse (LPN), concerning a 36 year old female patient with tuberculosis, and no known drug allergies, who on 26-MAR-2007 was vaccinated with Gardasil (lot #653736/0014U), as the result of "product confusion." The nurse stated, "HPV sounds like Hep B." Concomitant therapy included unspecified therapy for tuberculosis. In June or July of 2007 ("about 1-2 months ago"), she developed a "rash on her jaw line, below her ear and on her chest." The LPN stated that a specific treatment had not been recommended for the rash. At the time of this report, the patient had not recovered. Additional information has been requested. This is in follow-up to report (s) previously submitted on 9/17/2007. Initial and follow-up information has been received from a licensed practical nurse, concerning a 36 year old female patient with tuberculosis, and no known drug allergies, who on 26-MAR-2007 was vaccinated with GARDASIL (lot #653736/0014U), as the result of "product confusion." The nurse stated, "HPV sounds like HEP B." She did not know why the patient was given the wrong vaccine, except that the names sound alike. The labels, vials and cartons were not confused. Concomitant therapy included unspecified theraapy for tuberculosis. In June or July of 2007, ("about 1-2 months ago"), she developed a "rash on her jaw line, below her ear and on her chest." The LPN stated that a specific treatment had not been recommended for the rash. At the time of this report, the patient had not recovered. Additional information has been requested.

Other Meds: (therapy unspecified)

Lab Data: Unknown

History:

Prex Illness: Tuberculosis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **297443-2** **Related reports:** 297443-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Sep-2007	15-Sep-2007	3	16-Jan-2008	07-Feb-2008	MO	WAES0711USA01682	22-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1061U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2408AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	NULL	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug

Symptom Text: Information has been received from a registered nurse concerning a female who in May 2007, was vaccinated with Gardasil. Six months later, on 06-NOV-2007, the patient was dosed with her second dose. There were no problems reported. Additional information has been requested. Follow-up information has been received from a physician concerning a 13 year old white female with no pertinent medical history or drug reactions/allergies and no illness at the time of the vaccination who on 12-SEP-2007 was vaccinated with a first dose of Gardasil (lot# 658558/1061U) IM in the left arm at 8:00 AM. Concomitant therapy included a second dose of VARIVAX (lot# unknown) subcutaneous in the right arm and a first dose of MENACTRA (lot# U2408AA) IM in the right arm at 8:00 AM. On 15-SEP-2007 also reported as 17-SEP-2007, the patient's platelet count was 57K. On 19-Sep-2007 blood platelet count was 100 L and on 19-Nov-2007 the blood platelet count was 139 L. Subsequently, the patient recovered from platelet count 57k in December 2007. Additional information is not expected. This is in follow-up to report (s) previously submitted on 01/07/2008. Information has been received from a registered nurse concerning a female who in May 2007, was vaccinated with GARDASIL. Six months later, on 06-NOV-2007, the patient was dosed with her second dose. There were no problems reported. Follow-up information has been received from a physician concerning a 13 year old female with no pertinent medical history or drug reaction/allergies and no illness at the time of the vaccination who on 12-SEP-2007 was vaccinated with a first dose of GARDASIL (lot# 658558/1061U) IM in the left arm at 8:00 AM. Concomitant therapy included a second dose of VARIVAX (lot# unknown) subcutaneous in the right arm and a first dose of MENACTRA (lot# U2408AA) IM in the right arm at 8:00 AM. Concomitant therapy included a second dose of VARIVAX (lot# unknown) subcutaneous in the right arm and a first dose of MENACTRA (lot # U2408AA) IM in the right arm at 8:00 AM

Other Meds:

Lab Data: platelet count, 11/19/07, 139 L; platelet count, 09/19/07, 100 L; platelet count, 09/17/07, 57 L; complete blood cell; prothrombin time; INR, prothrombin time

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **300508-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Jun-2007	13-Jun-2007	0	18-Dec-2007	15-Jan-2008	WA	WAES0706USA05171	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0171U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cystitis, Drug exposure during pregnancy, Premature baby, Premature labour, Small for dates baby

Symptom Text: Information has been received via the Merck pregnancy registry, from a physician concerning a 15 year old female patient, who on 13-JUN-2007 was vaccinated with the first dose of Gardasil (Lot #655620/0171U). There was no concomitant medication. After receiving the vaccination (date not reported), the patient learned that she was pregnant (date of LMP and estimated date of delivery not reported). Follow up information received from the physician, via a company representative, indicated that the pregnancy resulted in a premature birth (date and gestational week not provided). The infant (gender not specified), also was "a low birth weight baby" (weight not specified). At the time of this report, the outcome and details of premature birth and low birth weight baby were unknown. No further details were provided. Additional information has been requested. This is in follow-up to report (s) previously submitted on 12/14/2007. Initial and follow-up information has been received via the Merck pregnancy registry, from a physician concerning a 15 year old female patient with an allergy to Penicillin, who on 13-JUN-2007 (also reported as March 2007) was vaccinated with the 0.5mL first dose of GARDASIL (Lot #655620/0171U). There was no concomitant medication. After receiving the vaccination (date not reported), the patient learned that she was pregnant (date of LMP and estimated date of delivery not reported) (also reported that the patient became pregnant in January 2007). Follow up information received from the physician, via a company representative, indicated that the pregnancy resulted in a premautre birth (date and gestational week not provided). The infant (gender not specified), also was "a low birth weight baby" (weight not specified). At the time of this report, the outcome and details of premature birth and low birth weight baby were unknown. It was reported that "everything is ok." The patient was hospitalized when she had the baby for a little over one day. No further details were provided. Fol

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP=unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **318212-3** **Related reports:** 318212-1; 318212-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		31-Mar-2010	01-Apr-2010	--	WAES1003USA04023	03-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myelitis transverse, Quadriplegia

Symptom Text: Information has been received from a company representative who overheard a physician mention information concerning a patient who on an unknown date was vaccinated with a dose of GARDASIL (route, dose and lot number not provided). On an unknown date, the patient experienced "transverse mellitus" after getting GARDASIL which resulted in quadriplegia. The patient's outcome was unknown at the time of reporting. Upon internal review, myelitis transverse and quadriplegia were considered to be an other important medical event. This is one of two reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **320705-2 (S)** **Related reports:** 320705-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		28-Apr-2010	29-Apr-2010	FR	WAES1004USA03737	29-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Erythema nodosum

Symptom Text: Information has been received from a gynecologist. This case is linked with case E2008-06930 (WAES # 0807USA04141) (Same source, same vaccine). A female (age unspecified) with no relevant medical history and no treatment had received a first dose of GARDASIL ((dose, duration, and lot number not reported) on an unspecified date in 2008. Less than 2 months after vaccination, the patient presented with erythema nodosum and was hospitalized. She did not receive any other injection of GARDASIL. At the time of reporting, the outcome was not specified. No further information expected. Other business partners numbers include: E2010-02448. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323863-3 (S)** **Related reports:** 323863-1; 323863-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jun-2008	01-Aug-2008	45	07-Jul-2010	08-Jul-2010	--	WAES0809USA02812	08-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2571AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Arachnoid cyst, Areflexia, Asthenia, Blood test normal, Body temperature normal, Cyst, Electroencephalogram, Fatigue, Full blood count normal, Gait disturbance, Guillain-Barre syndrome, Headache, Hypoaesthesia, Immunoglobulin therapy, Impaired driving ability, Lumbar puncture, Malaise, Metabolic function test, Muscular weakness, Myalgia, Nausea, Paraesthesia, Sensory disturbance, Sinusitis, Ultrasound bladder

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act concerning an 18-year-old female patient who on 17-JUN-2008 was vaccinated with a first dose of GARDASIL (lot # 660391/0063X) via intramuscular route into her right arm. Concomitant vaccination included the first dose of MENACTRA (lot # U2571AA) via intramuscular route into her right arm. On 11-AUG-2008, the patient experienced intolerable head/muscle pain, and muscle weakness "all over" arms. She also had "legs difficulty walking" and nausea. 911 was called and the patient was sent to emergency room for CT scan and was hospitalized. Her CT scan result was normal. Bloodwork and West Nile virus antibody test were performed with normal results according to her mother. On an unknown date, the patient was back to home with diagnosis of "possible viral infection". On 21-AUG-2008 the patient was weakness at doctor visit. She had a headache scaled 7; her not feeling well continued. The patient was sent to a neurologist emergency room for MRI scan and spinal tap. The patient also had electroencephalogram (EEG) on an unknown date. Results of MRI, spinal tap and EEG were not reported. Guillain-Barre Syndrome was diagnosed. On 26-AUG-2008, the patient was improving. The events required ER visit and hospitalization were considered to be serious. The original reporting source was not provided. The VAERS ID # is 323863. Additional information was obtained on request by the Company from the FDA under the Freedom of Information Act. Initial information has been received from a Registered Nurse (R.N.) concerning the female patient (also reported as 19 year old) who on 17-JUN-2008 was vaccinated with the first 0.5 ml dose of GARDASIL on 17-JUN-2008 (lot# 660391/0063X) along with concomitant vaccine of MENACTRA. On 11-AUG-2008 the patient experienced fatigue and walking problem. The patient was hospitalized from 21-AUG-2008 to 24-AUG-2008 and on 24-AUG-2008 the patient was diagnosed with Guillain Barre

Other Meds:

Lab Data: diagnostic laboratory, 08/??/08, blood test normal; computed axial, normal; chest X-ray, 08/21/08, negative; head computed axial, 08/01?/08, unremarkable except for some sinusitis of the sphenoid; nerve conduction study, 08/22/08, negative;

History: Arthroscopic surgery; Pregnancy

Prex Illness:

Prex Vax Illns:

Vaers Id: **325037-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	Unknown	Unknown		18-Aug-2008	16-Sep-2008	TX	WAES0807USA00419	05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Accidental exposure, Injection site anaesthesia, Injection site pain, Off label use

Symptom Text: Information has been received from a nurse concerning a male who on an unspecified date was inadvertently vaccinated with GARDASIL. No concomitant medication was reported. The patient experienced injection site pain and numbness. The patient sought medical attention in the office. On an unspecified date, he recovered. There was no product quality complaint. No further information is available. This is in follow-up to report (s) previously submitted on 8/14/2008. Information has been received from a nurse concerning a male who on an unspecified date was inadvertently vaccinated with GARDASIL. No concomitant medication was reported. The patient experienced injection site pain and numbness. The patient experienced injection site pain and numbness. The patient sought medical attention in the office. On an unspecifed date, he recovered. There was no product quality complaint. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **327008-3 (S)** **Related reports:** 327008-1; 327008-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jun-2008	26-Jun-2008	0	15-Jun-2010	16-Jun-2010	--		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Cognitive disorder, Convulsion, Fatigue, Gastrointestinal disorder, Loss of consciousness, Migraine, Nausea, Ovarian cyst, Pain, Rash, Skin lesion, Weight decreased

Symptom Text: My daughter received the GARDASIL vaccine in June of 2008 -only one of the three injections-and has been chronically ill for two years. Enough to be unable to attend school her freshman and sophomore year. She had severe gastro-intestinal issues early on -losing 20 pounds. Suffered with nausea 24/7 for eight months along with pain throughout her body, severe weakness, fatigue, seizures, cognitive issues, lapses in consciousness and outbreaks of facial lesions. She has improved over time but continues to suffer with the painful skin lesions -unless she takes VALTREX daily-, severe migraines -treating with neurologist, pain specialist and biofeedback doctor- and reoccurring ovarian cysts to which she has lost one of her ovaries at just 16 years old. PLEASE STOP THIS VACCINE. DOCTORS DO NOT KNOW HOW TO HELP THESE GIRLS. My daughter was extremely healthy prior to this - she rarely visited the doctor, athletic, active. This vaccine has changed her life.

Other Meds:

Lab Data: We have been to over 30 doctors. No one can help and most all tests come back normal - blood work, CAT SCANS, MRIs, etc. She did lose her ovary due to very large cyst and has had second surgery 6 months later for another ruptured cyst on th

History: no pre-existing conditions

Prex Illness:

Prex Vax Illns:

Vaers Id: **330679-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Jul-2008	09-Jul-2008	0	17-Oct-2008	13-Feb-2009	NY	WAES0810USA00028	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Intramuscular	
	IPV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Cold sweat, Myalgia, Pyrexia

Symptom Text: Information has been received from a physician concerning a 13 year old female patient with asthma, peanut allergy, shellfish allergy, Ipratropium (Atrovent) allergy, and ibuprofen (Motrin) allergy who on 09-Jul-2008 was vaccinated with the first dose of GARDASIL (lot# 660393/ 0067X). 0.5ml, intramuscularly. Concomitant therapy included unspecified asthma drug. The physician stated that on 09-Jul-2009, the patient developed muscle ache, weakness, clammy hands and was feverish for five hours after receiving GARDASIL. The physician reported that the patient received VERO, DTAP at the same office visit. No other symptoms reported. On 10-Jul-2008 the patient had recovered. Additional information has been requested. This is in follow-up to report (s) previously submitted on 10/14/2008. Initial and follow up information has been receivede from a physician concerning a 13 year old female patient with bronchial asthma, peanut allergy, shellfish allergy, honey allergy, strawberry allergy, ATROVENT allergy, and MOTRIN allergy who on 09-JUL-2008 at private doctor's office /hospital was vaccinated with the first dose of GARDASIL (Lot # 660393/0067X), 0.5 ml, intramuscularly. Concomitant vaccine include ADACEL. Concomitant drug included unspecified asthma drug. The physician stated that on 09-JUL-2008, the patient developed muscle aches, weakness, clammy hands and was feverish for 5 hours after receiving GARDASIL, and then recoved spontaneously the same day. No further information is available.

Other Meds: Therapy unspecified

Lab Data: None

History:

Prex Illness: Peanut allergy; Shellfish allergy; Hypersensitivity ; Hypersensitivity; Asthma

Prex Vax Illns:

Vaers Id: **332160-2 (S)** **Related reports:** 332160-1; 332160-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Mar-2007	20-Mar-2007	5	17-Jun-2010	18-Jun-2010	FR	WAES0901USA01085	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Back pain, Blood immunoglobulin G, Cranial nerve disorder, Eye pain, Gastrointestinal disorder, Hypoaesthesia, Laboratory test abnormal, Nausea, Neuromyelitis optica, Optic neuropathy, Pain in extremity, Rash, Spinal cord injury thoracic, Vaccine positive rechallenge, Visual acuity reduced, Vomiting

Symptom Text: This report was identified from a line listing obtained on request by the company from the FDA under the Freedom of Information Act. On 15-MAR-2007, a 13 year old female patient with eczema and a history of constipation and Raynaud's phenomenon and no pre vaccination illness was vaccinated with the first dose of GARDASIL. On 07-MAY-2007 the patient was vaccinated with the second dose of GARDASIL. On 14-SEP-2007 the patient received the third dose of GARDASIL. The patient experienced rashes after three vaccinations separately on 20-MAR-2007, 26-MAY-2007, 24-SEP-2007 and 27-NOV-2007. In February 2008 while on vacation the patient developed pain and decreased vision in left eye. MRI demonstrated enhancing lesion in left optic nerve, neuraxis. It was diagnosed as neuromyelitis optica (NMO). Three weeks ago the patient also had intermittent episodes low back pain and hospitalized for severe impaction. On 20-FEB-2008, the patient experienced left optic neuropathy and was treated with prednisone. Test was positive for NMO IgG. On 28-FEB-2008, MRI brain scan was performed to determine damage to optic nerve. On 27-MAR-2008 the diagnosis of NMO from clinic was known. Treatment with ritiximab was discussed. On 10-APR-2008, MRI thoracic spine was performed and discovered lesion. On 14-APR-2008 chest x-ray was performed (not result provided). On 16-MAY-2008, the patient experienced leg pain and numbness. On 20-MAY-2008 hospital visit confirmed diagnosis of NMO. On 15-JUN-2008 and 17-JUN-2008, the patient experienced back pain, numbness in right leg and stomach numbness. On 18-JUN-2008 MRI was performed and thoracic spinal lesion was confirmed. SOLU-MEDROL 1000 mg was taken. On 22-JUN-2008 the patient had back pain, numbness right leg and stomach numbness again. MEDROL tablet was started. On 14-JUL-2008 MRI thoracic follow up was performed (no result provided). On 20-AUG-2008 the patient experienced back pain. MRI was performed and the result noted thoracic lesion. On 06-OCT-2008, 07-OCT-2008 and 27-OCT-2008 the patient had ba

Other Meds: unknown

Lab Data: diagnostic laboratory test, 15Jan07; magnetic resonance imaging, 28Feb08, to determine damage to optic nerve; magnetic resonance imaging, 10Apr08, thoracic spine: lesion discovered; chest X-ray, 14Apr08; magnetic resonance imaging, 18Jun08,

History: constipation; Raynaud's phenomenon; eczema

Prex Illness:

Prex Vax Illns:

Vaers Id: **332160-3 (S)** **Related reports:** 332160-1; 332160-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Mar-2007	01-Dec-2006	-104	25-Jun-2010	28-Jun-2010	--	WAES1006USA03377	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Back pain, Blood immunoglobulin G, Cranial nerve disorder, Eye pain, Gastrointestinal disorder, Hypoaesthesia, Neuromyelitis optica, Nuclear magnetic resonance imaging brain abnormal, Optic neuropathy, Pain in extremity, Rash, Spinal cord injury thoracic, Vaccine positive rechallenge, Visual acuity reduced

Symptom Text: This report was identified from a line listing obtained on request by the company from the FDA under the Freedom of Information Act. On 15-MAR-2007, a 13 year old female patient with eczema and a history of constipation and Raynaud's phenomenon and no pre vaccination illness was vaccinated with the first dose of GARDASIL. On 07-MAY-2007 the patient was vaccinated with the second dose of GARDASIL. On 14-SEP-2007, the patient received the third dose of GARDASIL. The patient experienced rashes after three vaccinations separately on 20-MAR-2007, 26-MAY-2007, 24-SEP-2007 and 27-NOV-2007. In February 2008 while on vacation the patient developed pain and decreased vision in left eye. MRI demonstrated enhancing lesion in left optic nerve, neuraxis. It was diagnosed as neuromyelitis optica (NMO). Three weeks ago the patient also had intermittent episodes low back pain and hospitalized for severe impaction. On 20-FEB-2008, the patient experienced left optic neuropathy and was treated with prednisone. Test was positive for NMO IgG. On 28-FEB-2008, MRI brain scan was performed to determine damage to optic nerve. On 27-MAR-2008, the diagnosis of NMO from clinic was known. Treatment with ritiximab was discussed. On 10-APR-2008, MRI thoracic spine was performed and discovered lesion. On 14-APR-2008 chest X-ray was performed (not result provided). On 16-MAY-2008, the patient experienced leg pain and numbness. On 20-MAY-2008 hospital visit confirmed diagnosis of NMO. On 15-JUN-2008 to 17-JUN-2008, the patient experienced back pain, numbness in right leg and stomach numbness. On 18-JUN-2008 MRI was performed and thoracic spinal lesion was confirmed. Infusion SOLU-MEDROL 1000 mg was taken. On 22-JUN-2008 the patient had back pain, numbness right leg and stomach numbness again. MEDROL tablet was started. On 14-JUL-2008 MRI thoracic follow up was performed (no result provided). On 20-AUG-2008 the patient experienced back pain. MRI was performed and the result noted thoracic lesion. On 06-OCT-2008, 07-OCT-2008 and 27-OCT-2008 the pati

Other Meds: Unknown

Lab Data: diagnostic laboratory, 01/15/07; magnetic resonance, 02/28/08, to determine damage to optic nerve; magnetic resonance, 04/10/08, thoracic spine: lesion discovered; chest X-ray, 04/14/08; magnetic resonance, 06/18/08, thoracic spinal: lesion

History: Constipation; Raynaud's phenomenon; Eczema

Prex Illness:

Prex Vax Illns:

Vaers Id: **334817-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	22-Oct-2008	22-Oct-2008	0	17-Nov-2008	12-Feb-2009	TX	WAES0810USA04326	22-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Pain in extremity, Wrong drug administered

Symptom Text: Information has been received from a registered nurse concerning an 11 year old male who on 22-OCT-2008 was vaccinated with a dose of GARDASIL vaccine, IM. No problems reported. Follow up information was received from a physician who reported that the patient came into the office for Tdap vaccine (unspecified), MENACTRA and VARIVAX (Oka/Merck) and he mistakenly received GARDASIL. The physician reported that the child experienced some soreness in his arm and weakness, but nothing adverse. The physician stated the the child was fine. Additional information has been requested. This is in follow-up to report (s) previously submitted on 11/14/2008. Information has been received from a registered nurse concerning an 11 year old male who on 22-OCT-2008 was vaccinated with a dose of GARDASIL 0.5 mL, IM. No problems reported. Follow up information was received from a physician who reported that the patient came into the office for MENACTRA and VARIVAX and he mistakenly received GARDASIL. The physician reported that the child experiened some soreness in his arm and and weakness, but nothing adverse. The physician stated that the child was fine. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334826-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Apr-2007	01-Aug-2007	93	17-Nov-2008	12-Feb-2009	US	WAES0810USA04517	22-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a female consumer, concerning her 13 year old daughter with no medical history or allergies who on 12-FEB-2007 was vaccinated with the first dose of GARDASIL, the second dose on 30-APR-2007 and the third dose on 07-AUG-2007. There was no concomitant medication. The consumer reported that, in August 2007, "not too long after receiving the third dose of GARDASIL", the patient started to have severe stomach pain on her upper left side. The reporter stated that her daughter's pain level on a scale of 1 to 10 was a 7. The consumer reported that the patient had blood work, ultra sounds and CAT scans done and they all came back normal. The reporter stated that the next time the patient saw the physician they may have to "put a scope in her to check out her stomach area". The patient was not recovered at the time of this report. The patient sought medical attention with a physician. No further information is available. This is in follow-up to report (s) previously submitted on 11/14/2008. Information has been received from a female consumer, concerning her 13 year old daughter with no medical history or allergies who on 12-FEB-2007 was vaccinated with the first dose of GARDASIL, the second dose on 30-APR-2007 and the third dose on 07-AUG-2007. There was no concomitant medication. The consumer reported that, in August 2007, "not too long after receiving the third dose of GARDASIL", the patient started to have severe stomach pain on her upper left side. The reporter stated that her daughter's pain level on a scale of 1 to 10 was a 7. The consumer reported that the patient had blood work, ultra sounds and CAT scans done and they all came back normal. The reporter stated that the next time the patient saw the physician they may have to "put a scope in her to check out her stomach area". The patient was not recovered at the time of this report. The patient sought medical attention with a physician. This is an amended report. The vaccination date of the third dose of GARDAS

Other Meds: None

Lab Data: Diagnostic laboratory, normal; Ultrasound, normal; Computed axial, normal.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342045-3 (S)** **Related reports:** 342045-1; 342045-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	18-Oct-2007	18-Oct-2007	0	28-Jun-2010	30-Jun-2010	--		30-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Collagen disorder, Immune system disorder

Symptom Text: Please read the email I sent an official at the FDA this past October concerning the GARDASIL vaccine. In which no action has taken place. As I stressed during our conversation the FDA is limited to take certain actions by law. The office has the responsibility to contact the agency and address these issues with the secretary immediately. If the FDA can unleash a vaccine so powerful that we cannot get our children help then the FDA has a major problem on their hands. This vaccine did not have adequate testing and I am demanding the agency to contact and address this agency immediately for a solution. I don't care if this is standard protocol or not. I don't care if the agency hires a hundred scientist, doctors, and chemist, but our children will get the help they rightly deserve. If our doctors are not smart and experienced enough to diagnose our kids then maybe you should take this vaccine off the market. Its not just my daughter suffering please get to website and you will get a full ideas of how many children are sick and thats not even the full extent of how many children have been injured around the world. I'm also in the process of retrieving contact information in order for the FDA to contact her to discuss the immune disorders during the clinical trials. Merck has been allowed to market this drug falsely and should be held accountable for their actions. No one commercial states the side effects that occurred during the clinical trials for example, arthritis, Guillian Barre Syndrome, thrombosis and more which clearly states this information in their insertion letter given after the shot has been injected. This dose not even touch the side effects which haven been reported in VAERS, but Merck should be held accountable for stating the truth in the T. V. commercials. My daughter along with all these other little girls should NOT have to suffer for over two years and carry the mental and physical burden of a diagnosis "unknown". If the agency can hold a special meeting and send my relatives overseas and fight

Other Meds: It was a hard to put all the information provided in the series due to the field do not have enough lines to submit. My daughters lot numbers and dates are all outlined in detail on the vaers.org site. Along with the other vaccines she was

Lab Data: I received a call from the VAERS.org part of the FDA in which they are going to pull all my daughter's medical records. I personally visited each office and gave them my consent to send the FDA any information they needed in order to help m

History: No pre-existing conditions. She was a volleyball player, healthy diet, only drank maybe three soft drinks a year, drug free, and has not had sex. A child with a 4.4 GPA now suffering due to a sloppy vaccine.

Prex Illness:

Prex Vax Illns:

Vaers Id: **344175-2 (S)** **Related reports:** 344175-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	F	01-Dec-2008	Unknown		19-May-2010	20-May-2010	--	WAES0904USA01164B1	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Apgar score normal, Continuous positive airway pressure, Drug exposure during pregnancy, Intensive care, Laboratory test normal, Premature baby, Respiratory distress, Retinal disorder, Small for dates baby

Symptom Text: Information has been received from a medical assistant concerning one of twin babies. The baby's 18 year old mother was vaccinated with the first and second 0.5 ml dose of GARDASIL by different provider and was vaccinated IM with the third 0.5ml dose of GARDASIL (lot #: 659962/1740U) on 01-DEC-2008. The mother's last menstrual period was 19-NOV-2008 and estimated delivery date was 05-SEP-2009. The medical assistant reported that the baby was born about 1 month early, in approximately August 2009, but as far as she knew, the baby was born normal and healthy. Follow-up information was received from a pediatrician via medical records. It was reported that the mother delivered twin babies (one male and one female) on 13-JUL-2009. The baby girl was born on 13-JUl-2009, 32 2/7 weeks of gestation via C-section for breech position. The baby was transferred to neonatal intensive care unit (NICU) for 18 days, and on continuous positive airway pressure (CPAP) for three days. Active medications included vitamins (unspecified) (POLY-VI-SOL) 0.5 ml PO BID. On 13-AUG-2009, the baby's weight was 5 pounds, 15 ounces, length was 18.5 inch, and head circumference was 13 inch. Her body temperature was 98, pulse was 136, and respiratory rate was 40. Physical examination showed the baby was alert, premature and active. The assessment was the female baby was one month old, premature, was doing well, and breech of birth. The baby continued diet Neosure 22 kcal/ounce and vitamins (unspecified) (POLY-VI-SOL). An ultrasound for hips was scheduled. Barlow and Ortolani tests were negative. The baby would be arranged "for syringes, monthly injection". On 04-SEP-2009, the baby had hip click alignment check. Ultrasound infant hips with physician guided was performed which showed both hips were within normal limits. The mother's experience has been captured in WAES # 0904USA01164. The twin baby's experience has been captured in WAES # 0904USA01164B2. Additional information has been requested. All available medical records will be provided upon r

Other Meds: betamethasone; loratadine

Lab Data: Ultrasound, 09/04/09, hip click alignment check: both hips were within normal limits The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: CXR normal with no abnormality. U/S of hea

History: Unknown The following information was obtained through follow-up and/or provided by the government. PMH: twin gestation, maternal use of steroids, maternal exposure to vaccination during pregnancy, premature rupture of membranes, breach presentation, teen pregnancy (mother), maternal PIH. Allergies: none.

Prex Illness:

Prex Vax Illns: Drug exposure during~HPV (Gardasil)~2~0.00~Sibling|Neonatal respiratory; Premature baby 33 to 36; Retinal disorder~HPV (Gardasil)~3~0.00~Sibling

Vaers Id: **346148-2 (S)** **Related reports:** 346148-1; 346148-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-May-2008	Unknown		08-Jul-2010	09-Jul-2010	MD	WAES1006USA04639	09-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Blood test, Central venous catheterisation, Convulsion, Impaired driving ability, Impaired work ability, Laboratory test, Metabolic function test, Sinusitis, Syncope

Symptom Text: Information has been received from a consumer concerning her 21 year old daughter with no pertinent medical history and no known drug allergies who in March 2008 and May 2008 was vaccinated with a first and second doses of GARDASIL respectively (lot # not reported). Concomitant therapy included birth control medicine (unspecified). The consumer stated that the day after the second dose of GARDASIL in May 2008, the patient went to her internship/work and the mother was called because the patient fainted. She was taken to the unspecified emergency room and released. She again fainted at her internship/work and was taken to emergency room, where she had 8 witnessed seizures and was discharged with a diagnosis of a sinus infection. She then attended a barbeque, where the host called the mother to tell her that patient had a full blown seizure, not a fainting episode. She was then admitted to the hospital for 6 days with multiple tests done (metabolic test, blood test and many others, results not provided). The infectious disease physician suggested that the seizure activity may be related to GARDASIL injection. Patient was discharged to home, with intravenous access (peripherally inserted central catheter (PICC) line) for antibiotic therapy and placed on KEPPRA for anti-seizure therapy. She lost her internship, and had not been able to drive for the past two years. She had not had a full blown seizure but she can "feel them coming on". At the time of the report, the patient had not recovered from the seizure. The outcome of the sinus infection was unknown. The consumer also noted that the patient has a twin sister (unknown whether the twin was vaccinated with GARDASIL). Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **346148-3 (S)** **Related reports:** 346148-1; 346148-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-May-2008	Unknown		08-Jul-2010	09-Jul-2010	MD	WAES1006USA04639	12-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Blood test, Convulsion, Impaired driving ability, Impaired work ability, Laboratory test, Metabolic function test, Sinusitis, Syncope

Symptom Text: Information has been received from a consumer concerning her 21 year old daughter with no pertinent medical history and no known drug allergies who in March 2008 and May 2008 was vaccinated with a first and second doses of GARDASIL respectively (lot# not reported). Concomitant therapy included birth control medicine (unspecified). The consumer stated that the day after the second dose of GARDASIL in May 2008, the patient went to her internship/work and the mother was called because the patient fainted. She was taken to the unspecified emergency room and released. She again fainted at her internship/work and was taken to emergency room, where she had 8 witnessed seizures and was discharged with a diagnosis of sinus infection. She then attended a barbecue, where the host called the mother to tell her that patient had a full blown seizure, not a fainting episode. She was then admitted to the hospital for 6 days with multiple tests done (metabolic test, blood test and many others, results not provided). The infectious disease physician suggested that the seizure activity may be related to GARDASIL injection. Patient was discharged to home, with intravenous access (Peripherally inserted central catheter (PICC) line) for antibiotic therapy and placed on KEPPRA for anti-seizure therapy. She lost her internship, and had not been able to drive for the past two years. She had not had a full blown seizure but she can "feel them coming on". At the time of the report, the patient had not recovered from the seizure. The outcome of the sinus infection was unknown. The consumer also noted that the patient has a twin sister (unknown whether the twin was vaccinated with GARDASIL). Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **346200-2** **Related reports:** 346200-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-Apr-2009	05-May-2009	6	18-May-2010	10-Jun-2010	KY	WAES0905USA00527	11-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	UF471BA	0	Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	0125Y	1	Unknown	Subcutaneously	
HEPA	MERCK & CO. INC.	1604X	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2869AA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	1312X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash erythematous, Rash papular, Varicella post vaccine

Symptom Text: Information has been received from a physician concerning a female patient who on 29-APR-2009 was vaccinated subcutaneously with 0.5 ml of the second dose of VARIVAX (Merck) (Lot:663546/0125Y). On the same day the patient received VAQTA (MSD) (lot # 663548/1604X), intramuscularly in her left arm, GARDASIL (MSD) (lot # 661846/1312X), MENACTRA and ADACEL. On an unspecified date the patient presented to the office with a diagnosis of chicken pox located behind her one ear. At the time of reporting, on 05-MAY-2009, the patient's chicken pox persisted. Follow-up information was received from registered nurse who reported that on 05-MAY-2009 experienced a rash and first noticed it behind her ears, now on her stomach and her arms. The rash behind her ear was a fine red rash. The patient developed a papular rash scattered at her thorax and extremities. The nurse suggested to keep her skin clean and dry and the patient took BENADRYL for pruritus. The patient was given hydrocortisone for behind her ears only. The outcome of the patient was unknown. No further information is available.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **346337-2 (S)** **Related reports:** 346337-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jun-2007	15-Jun-2007	14	15-Jun-2010	16-Jun-2010	--		29-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Anxiety, Arthralgia, Chronic inflammatory demyelinating polyradiculoneuropathy, Feeling abnormal, Infection, Insomnia, Lyme disease, Menstruation irregular, Myalgia, Postural orthostatic tachycardia syndrome, Rheumatoid arthritis, Streptococcal bacteraemia, Upper respiratory tract infection, Urinary tract infection

Symptom Text: Since receiving the GARDASIL vaccine, my daughter has been diagnosed with POTS, rhuemotoid arthritis, CIPID, various infections including strep syndrome, lyme, URIS, UTIS, irregular periods - hasn't had a period now from Sept 2009 - June 2010. She developed strep multiple times after the first vaccine 12/2006, then various Utis and Uria, through the second 2/2007, and by the 3rd vaccine she developed whole body joint and muscle pain, insomnia, anxiety, brain fog. Rheumatoid arthritis was diagnosed April 2009, Pots was diagnosed May 2009 and CIPD in May 2010. She is disabled and has not recovered. This vaccine has destroyed her health and needs to be black boxed or taken off the market.

Other Meds:

Lab Data: Blood work 2007 - 2010; Cat Scan Jan 2009; Cat Scan June 2010; MRI neck/spine April 2009; Tilt table May 2009; Halter Monitor June 2009; Spect Scan of Brain July 2009

History: Mono May 2006; Hepatitis C Dec 2010

Prex Illness:

Prex Vax Illns:

Vaers Id: **348807-3 (S)** **Related reports:** 348807-1; 348807-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Apr-2009	24-Apr-2009	1	15-Jun-2010	16-Jun-2010	--		22-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1423X	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Chest pain, Dizziness, Dyspnoea, Fatigue, Headache, Muscular weakness, Myalgia, Nausea, Neuralgia, Neuropathy peripheral, Posture abnormal, Skin burning sensation

Symptom Text: My daughter was given the first GARDASIL vaccine on 4/23/09 and the very next day began having adverse reactions. She started off with symptoms of nausea, dizziness, headache, and fatigue. As the days passed, she began experiencing muscle weakness so extreme that she could not hold her own head up, muscle aches, joint pain, nerve pain to feet and legs, burning skin, chest pain, shortness of breath. She was diagnosed with peripheral neuropathy by a pediatric neurologist that stated that this was a direct result of the GARDASIL vaccine. She has had countless test including, CT scans, MRI's, blood draws, ER visits and specialist visits. It is not one year past the first vaccine and my once healthy daughter continues to have dizziness, fatigue, chest pain, intermittent muscle weakness, chronic fatigue. This vaccine has effected her ability to go away to college because she cannot live in a dormitory situation because her body is not healthy enough to withstand the required meningitis vaccine. This vaccine has destroyed the life of a once healthy girl. The good the vaccine does is not enough to out way the harm when you are the one that has been harmed!!!! This is a bad vaccine. It is destroying the lives of healthy young girls. Do something!

Other Meds:

Lab Data: CT Scan of spine 6/09; MRI brain 6/09; Epstein Barr; C-reactive protein; CBC, 5/09; CXR, numerous; EKG, numerous

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **349171-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2009	01-May-2009	0	15-Jun-2009	14-Jul-2009	US	WAES0905USA00270	05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MMR	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer concerning herself with no previous pregnancies and no reported past drug history who on 01-MAY-2009 was vaccinated with a dose of GARDASIL. Secondary suspect vaccine given on the same day included MMR II (manufacturer unknown). There was no concomitant medication reported. It was reported that on 01-MAY-2009, in the evening after getting the vaccines the patient got really sharp belly pain. On 02-MAY-2009 a home pregnancy test was done and the result was positive. The last menstrual period of the patient was on 25-APR-2009 and the estimated delivery date was 30-Jan-2010. Additional information has been requested. This is in follow-up to report (s) previously submitted on 6/12/2009. Information has been received from a consumer, for GARDASIL, a Pregnancy Registry product, concerning herself with no previous pregnancies and no reported past drug history who on 01-MAY-2009 was vaccinated with a dose of GARDASIL. Secondary suspect vaccine given on the same day included MMR II (manufacturer unknown). There was no concomitant medication reported. It was reported that on 01-MAY-2009, in the evening after getting the vaccines the patient got really sharp belly pain. On 02-MAY-2009 a home pregnancy test was done and the result was positive. The last menstrual period of the patient was on 25-APR-2009 and the estimated delivery date was 30-Jan-2010. Additional information has been requested. This is a consolidation of two reports concerning the same patient. It has been determined that WAES # 0905USA00271 is a duplicate of WAES # 0905USA00270. Therefore, WAES # 0905USA00271 is being deleted from our files and the reports consolidated into WAES # 0905USA00270.

Other Meds: None

Lab Data: Beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP= 4/25/2009)

Prex Vax Illns:

Vaers Id: **351718-2** **Related reports:** 351718-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-May-2009	25-Jun-2009	28	28-Apr-2010	28-Apr-2010	PA		30-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Grand mal convulsion, Loss of consciousness, Vocal cord disorder

Symptom Text: vocal chords seizing made me go in her room to see her having a gran mal seizure then pass out and wake not knowing anyone or anything. Continues having 4 more seizures since.

Other Meds: Swimmer Ear meds given that day

Lab Data: MRI EEG CAT Scan

History: None

Prex Illness: Swimmers Ear

Prex Vax Illns:

Vaers Id: **351972-2 (S)** **Related reports:** 351972-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Nov-2007	Unknown		02-Aug-2010	03-Aug-2010	GA		05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Amnesia, Balance disorder, Convulsion, Dyspnoea, Headache, Hypoaesthesia, Joint swelling, Monoplegia, Pain, Paraesthesia, Weight decreased

Symptom Text: Diagnosed w/...mono, Gullain Barre, CMT, lupus. All of this has been wrongful dx per her MD. She struggles everyday w/ seizures, problems breathing, balance, amnesia, electric shock through her body, weight loss, pain all over her body...swelling in joints, numbness, paraylsis left leg, headaches, short memory loss. Everyday there seems to be new symptom's! This is ridiculous that the FDA, CDC and everyone else that is involved in this FATAL DRUG has not discontinued this! It's all a money gimmick!!! My daughter has to have 24/7 care...that is only 15 yrs old. Before this vaccine she was perfectly healthly!!

Other Meds:

Lab Data: MRI'S, EEG'S, CT SCANS, NERVE CONDUCTOR, LOTS OF LAB WORK, SPINAL TAPS, URINALYSIS. THESE TEST HAVE BEEN DONE MANY NUMEROUS TIMES!!!

History:

Prex Illness:

Prex Vax Illns: FLU LIKE SYMPTOMS~HPV (Gardasil)~1~14.00~Patient|BODY PAINS~HPV (Gardasil)~2~14.17~Patient|GULLIAN BARRE, LUPUS, CMT, BODY PAIN, MUS

Vaers Id: **353037-2 (S)** **Related reports:** 353037-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Oct-2008	14-Oct-2008	0	16-Jul-2010	19-Jul-2010	TN	WAES1007USA00538	19-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Alopecia, Asthenia, Chest pain, Fatigue, Gastrointestinal disorder, Nausea, Oedema peripheral, Oligomenorrhoea, Pain, Pain in extremity, Swelling face, Vomiting

Symptom Text: Information has been received from a consumer's mother concerning a 15 year old female with penicillin allergy who on 14-OCT-2008 was vaccinated with the first dose of GARDASIL (lot # 659964/1978U) on her right arm, on 29-DEC-2008 with the second dose (lot # 659964/1978U) on the left arm, and on 14-JUL-2009 with the third dose (lot # 659964/1978U) on her right arm. Concomitant therapy included gabapentin, nortriptyline and omeprazole. On 14-OCT-2008 the patient experienced weakness, tiredness, chest pain, swelling on face and hands, hair loss, leg pain, menstrual cycle lasting a month, and could not keep food down. The reporter stated she had taken her daughter to see a specialist. It was reported that her "daughter still could not hold any food down and her stomach still hurts". CT Scan, Blood work, MRI, Nerve Conductions Test, PMG and Spinal Tap was performed and "all her tests (unspecified) came out negative". The patient's physician stated that patient was still experiencing feelings of nausea and her stomach still hurt, he ruled out a problem with her gallbladder. He was referring her to a Gastrointestinal Specialist for an endoscopy. The physician also reported that patient was diagnosed with Amplified Pain Syndrome. The patient required hospitalization or prolonged. The patient had not recovered at the time of report. The events of "weakness, tiredness, chest pain, swelling on face and hands, hair loss, leg pain, menstrual cycle lasting a month, could not keep food down, her stomach still hurts, amplified pain syndrome and nausea were considered to be disabling by the patient's mother. Follow up information received a medical assistant who took this call but asked the questions of the physician who was in the background. According to the medical assistant, the GARDASIL vaccinations were given elsewhere (no details in the chart). Regarding the concomitant medications (gabapentin 600mg TID, nortriptyline 10mg taken at night, and omeprazole 40mg once a day) listed by the consumer, the medical assistant said t

Other Meds:

Lab Data: computed axial, negative; diagnostic laboratory, Blood work, negative; magnetic resonance, negative; spinal tap, negative; diagnostic laboratory, ?/?/09, autonomic reflex study, negative; diagnostic laboratory, ?/?/09, 69 %, Exercise physio

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **356323-2 (S)** **Related reports:** 356323-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Apr-2010	30-Apr-2010	--	WAES1004USA03638	30-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abnormal behaviour, Activities of daily living impaired, Bipolar disorder, Brain injury, Convulsion, Increased appetite, Insomnia, Malaise, Narcolepsy, Pain, Vomiting

Symptom Text: Information has been received from a consumer via TV, concerning on an unspecified age consumer's daughter who from 2007 to 2008 was vaccinated with a series of GARDASIL (route and lot number not reported). The mother was claiming her daughter suffered from seizures and got brain damage after getting the vaccination. It was reported that has been sick for the past three years with uncontrollable vomiting and seizures that left her brain damaged. The mother reported that shortly after, the patient reportedly went from being a happy, honor-roll student to a completely different person. The mother said that the doctor told her that her daughter's condition was behavioral, not medical. "They had put her on psych meds, thinking she was bi-polar or something like that.", but the mother was convinced that the injections were to blame. According to the mother, her daughter needed constant care. She said the refrigerator was locked because she has urges to eat constantly. It was reported that her daughter was narcoleptic during the middle of the day, could not sleep at night and was in constant pain. The patient said she wanted to go back to school but she could not. At the time of the report the outcome of the patient was unknown. Can not go back to school and she needed constant care were considered to be disabling. Upon internal review, seizures and brain injury damage were determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **358125-3** **Related reports:** 358125-1; 358125-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Sep-2009	Unknown		12-Jul-2010	13-Jul-2010	--	200904103	13-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2773AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0653X		Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	500687P		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy, Nausea, Ovarian cancer

Symptom Text: Initial report was received from a health care professional on 24 September 2009. A 15-year-old pregnant female patient had received a 0.5 mL intramuscular left deltoid injection of ADACEL, lot number C2773AA, and a 0.5 mL intramuscular left deltoid injection of HPV vaccine (manufacturer Merck, lot number 0653X) and a intranasal dose of FLUMIST (manufacturer MedImmune, lot number 500687P) on 17 September 2009. The vaccine was administered by a school nurse and it was unknown at the time of the vaccination that the patient was pregnant. The patient had no pre-existing medical conditions and no prior pregnancies. Her last menstrual period occurred on 01 August 2009 and her expected date of confinement was 09 May 2010. At the time of report, the patient had not experienced any adverse events since vaccination. Follow-up information was received 19 March 2010 from a health care professional. From new information received, it was reported that the patient had received ZOFRAN 4mg since 28 September 2009 for "ovarian carcinoma refractory (nausea)". Based upon this new information, this case has been upgraded from nonserious to serious. Additional maternal drug exposures included Iron 325mg beginning 16 December 2009 for anemia, and supplemental prenatal vitamins beginning 28 September 2009. The patient's last menstrual period occurred on 02 August 2009 (previously reported as 01 August 2009). Significant medical conditions were reported as "teen, anemia" and the patient was also noted to have had a family history of diabetes and HTN (hypertension). Prenatal tests included alpha feto protein on 18 November 2009 and an ultrasound on 23 December 2009, both with normal findings. An outcome was not reported for the event of ovarian carcinoma refractory nausea and anemia. Documents held by sender: None.

Other Meds: Prenatal vitamins; ZOFRAN; Iron

Lab Data: 18/Nov/2009: Alpha Feto Protein (normal); 23/Dec/2009: Ultrasound (normal)

History: Pregnant, LMP date: 02/AUG/09 Sex: Female. The patient had no previous pregnancies. From information received on 19 March 2010, the patient had a family history of diabetes and HTN (hypertension).

Prex Illness:

Prex Vax Illns:

Vaers Id: **363747-2** **Related reports:** 363747-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jun-2009	01-Jun-2009	0	19-May-2010	20-May-2010	--	WAES0906USA05186	03-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0471Y	0	Unknown	Subcutaneously	
TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	0653X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed visiting nurse for GARDASIL, a Pregnancy Registry product, concerning a 17 years old female with some unspecified hypertension medication allergies and a history of normal pregnancy who on 01-JUN-2009 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot number 661841/0653X) while she was pregnant. Concomitant therapy included VARIVAX (lot number 662373/0417Y), 0.5 ml, SQ on 01-JUN-2009. Other concomitant therapy included meningococcal vaccine (unspecified) and DTAP and BACTRIM for urinary tract infection on 01-JUN-2009. On 01-JUN-2009 a pregnancy test was conducted but the test was negative. No adverse reactions reported. Phone call was made for medical attention on 25-JUN-2009. The patient was referred to an obstetrician. The patient's LMP was 29-MAY-2009 and the EDD was 5-MAR-2010. At the time of the report, the patient's outcome was unknown. Follow up information was received from a nurse practitioner. It was reported that the 17 year old patient had one previous full term delivery. It was unknown if there were any birth defects or infant complications with her previous pregnancy. Follow up information was received from a nurse practitioner. It was confirmed that LMP for the pregnancy was 29-MAY-2009 and the patient did have a positive pregnancy test on 25-JUN-2009. On approximately September 2009 ("may be in the fall"), the patient had a miscarriage. The reporter did see the patient on 12-DEC-2009 and the patient reported that her LMP at that visit was 24-NOV-2009, so the miscarriage was prior to that time. The patient was not pregnant at the December visit. The patient did not have a history of prior miscarriage and does have a 2 year old child. It was also reported that the patient did not have a history of drug abuse. It was not known who the patient saw for her pregnancy care. No further information is available.

Other Meds:

Lab Data: beta-human chorionic, 06/01/09, negative; beta-human chorionic, 06/25/09, positive

History: Normal pregnancy; Drug abuse

Prex Illness: pregnancy NOS (LMP = 5/29/2009); urinary tract infection; drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **368235-2** **Related reports:** 368235-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Dec-2007	18-Jan-2008	28	26-May-2010	26-May-2010	OH		27-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	FLU
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Fall, Head injury, Syncope

Symptom Text: Felt dizzy and lightheaded. Fainted. Fell backwards and cracked head on concrete. Seizure lasting 2 minutes. Went to hospital in ambulance. Treated and released same day.

Other Meds:

Lab Data: This has recurred four times in the ensuing years. Patient has undergone repeated tests and has seen many specialists. Problem continues.

History: airborne allergies

Prex Illness: sinus congestion

Prex Vax Illns:

Vaers Id: **370369-2 (S)** **Related reports:** 370369-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	08-Aug-2007	02-Oct-2007	55	03-May-2010	04-May-2010	--	WAES1004USA00916	04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0469U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Ataxia, Back pain, Balance disorder, Hypoaesthesia, Muscular weakness, Musculoskeletal stiffness, Myelitis transverse, Neck pain, Nystagmus, Pain, Paraesthesia, Paralysis, Pneumonia mycoplasmal

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 08-AUG-2007, a 21 year old female patient with ampicillin and amoxicillin allergy was vaccinated intramuscularly with the first dose of GARDASIL (lot#0469U) into the right arm. Concomitant therapy included BACTRIM. 55 days later, on 02-OCT-2007 the patient awoke in the morning with severe neck and upper back pain. She developed numbness and tingling from shoulders down and then quickly turned into weakness then paralysis from shoulders down. She went to emergency room and was diagnosed clinically with T4 transverse myelitis. On 02-DEC-2009, DC summary and hospital records received for date of service from 02-OCT-2009 to 08-OCT-2007: patient awoke on morning of 02-OCT-2009 with stiff neck, shooting pain down both arms and progressive weakness of bilateral upper extremities. She was admitted to hospital and was treated with steroids with initial improvement of left upper extremity weakness. She developed gait ataxia during hospital stay which also improved by discharge. She was diagnosed with mycoplasma pneumoniae and infectious disease consult obtained, she was treated with antibiotic. Right upper extremity significant weakness remained. She discharged home to continue physical therapy as outpatient. Doctor diagnosis was: transverse myelitis, positive mycoplasma in serum with cerebrospinal fluid (CSF). On 02-DEC-2009, neurology records received for date of service: 12-OCT-2007, 20-NOV-2007, 10-AUG-2008, 01-JAN-2008, 15-FEB-2008, the patient presented with continued numbness of left leg with loss of pain and temperature sensation; persistent weakness of right arm. She was diagnosed with transverse myelitis, mild lateral gaze nystagmus. On 07-DEC-2009, neurology consult received for the date of service 02-DEC-2009, the patient was diagnosed with transverse myelitis, she had full movement of affected arm with continued weakness, and she had no pain. She had numbness of left leg to pa

Other Meds: BACTRIM

Lab Data: Magnetic resonance, MRI of C- T-spine and brain initially negative; Diagnostic laboratory, positive mycoplasma in serum with CSF; Cerebrospinal fluid, negative

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **374854-2 (S)** **Related reports:** 374854-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	25-Sep-2009	16-Nov-2009	52	26-Apr-2010	27-Apr-2010	--	WAES1004USA00853	28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y		Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Asthenia, Autoimmune thrombocytopenia, Blood test abnormal, Contusion, Cough, Diarrhoea, Epistaxis, Fatigue, Feeling hot, Haematochezia, Headache, Hypoaesthesia, Idiopathic thrombocytopenic purpura, Immunoglobulin therapy, Injection site pain, Lip disorder, Oral contraception, Paraesthesia, Paralysis, Petechiae, Rash, Sensation of heaviness, Thrombocytopenia, Upper respiratory tract congestion

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Act. On 25-SEP-2009, a 25 year old female was vaccinated in the right arm with the first dose of GARDASIL (lot number 663452/0671Y) (route unknown). Concomitant medication included TRIVORA, once daily and albuterol PRN, for seasonal and pet allergies. Two months later, on 16-NOV-2009 (also reported as 19-NOV-2009), the patient went into her doctor with petechiae (red blood dots) on her legs, excessive bruising on her legs and arms, and mouth lumps (inside lower lip). The patient took a blood lab and when the results came in, the patient was at 8,000 platelet count and told to go to the emergency room (ER) right away. Treatment (steroids alone) lasted for 2 days, and the patient had to go back to the ER, this time with arm numbness/temporary paralysis added to the issue. Treatment with a stronger medication Rho(D) immune globulin (ANTI-D) was administered, but again, two days later, the patient was back in the ER. A third treatment was administered (IVIG), and it lasted two weeks. The patient was scheduled to go back to the hospital for admission to do another dose of this. Aside from pain at the injection site for over a month, the patient had also now been diagnosed with the autoimmune disease thrombocytopenia (low blood platelets) which she had been dealing with for over a month at an aggressive level, and it showed no signs of getting better. During this condition, she has had arm numbness/temporary muscle paralysis, as well. The patient had been admitted into the hospital 3 times, and had to go back again in a few days, as she dropped again. On 23-DEC-2009, PCP medical records received. Service dates 11/19/09 to 12/21109. Included emergency department (ED) visit 21-NOV-2009. Assessment: Idiopathic Thrombocytic Purpura, Patient complained of feeling warm, fatigue, Cough, congestion, Oral contraceptive use, Hematochezia, Paresthesia, Bruising on forearms, Presents at ED with petechiae, Multiple bruises thigh

Other Meds: albuterol; TRIVORA

Lab Data: platelet count, 11/16?/09, 8 000; platelet count, 11?/??/09, 3 000; platelet count, 11/??/09, 12

History:

Prex Illness: Allergic reaction to antibiotics; Penicillin allergy; Asthma

Prex Vax Illns:

Vaers Id: **375681-2 (S)** **Related reports:** 375681-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Apr-2007	19-Apr-2007	2	11-May-2010	12-May-2010	--	WAES1004USA00974	12-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Adenotonsillectomy, Anxiety, Arthralgia, Asthenia, Candidiasis, Change of bowel habit, Chest pain, Chills, Cold sweat, Colonoscopy, Condition aggravated, Confusional state, Constipation, Convulsion, Cough, Diarrhoea, Dizziness, Dyspepsia, Dysphagia, Dysphonia, Dyspnoea, Ear pain, Fatigue, Feeling hot, Gastrooesophageal reflux disease, Headache, Heat exhaustion, Hyperhidrosis, Hypermobility syndrome, Hypersensitivity, Hypersomnia, Hypophagia, Irritable bowel syndrome, Lethargy, Malaise, Memory impairment, Muscle spasms, Myalgia, Myofascial pain syndrome, Nasal congestion, Nausea, Neck pain, Night sweats, Odynophagia, Oropharyngeal pain, Pain, Palpitations, Paraesthesia, Pharyngitis, Pyrexia, Rash, Somnolence, Staring, Tinnitus, Urticaria, Vomiting, Weight increased

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 13 year old female with hypothyroidism, depression, allergy to ADDERAL, LAMICTAL, rapid eye blinking and a history of bipolar, asthma, tics, anxiety, behavioral issued, allergy to AUGMENTIN, and a history of fibromyalgia. The patient had a previous vaccine illness of seizure and influenza H1N1, the patient was vaccinated with influenza H1N1 (manufacturer unknown). On 17-APR-2007 the patient was vaccinated with the first dose of GARDASIL (lot# 653937/0637F) IM. On 19-APR-2007 the patient experienced abdominal pain, activities of daily living impaired, adenotonsillectomy, anxiety, arthralgia, asthenia, candidiasis, change of bowel habit, chest pain, chills, conditions aggravated, confusional state, convulsion, cough depression, diarrhoea, dizziness, dysphagia, dysphonia, dyspnoea, ear pain, fatigue, feeling hot, fibromyalgia, gastroesophageal reflux disease, headache, heat exhaustion, hyperhidrosis, hypermobility syndrome, hypersensitivity, hypersomnia, hypophagia, irritable bowel syndrome, lethargy, malaise, memory impairment, muscle spasms, myalgia, myofascial pain syndrome, nasal congestion, nausea, neck pain, night sweats, odynophagia, oropharyngeal pain, pain, palpitations, paraesthesia, pharyngitis, pyrexia, rash, sleep disorder, somnolence, staring, tinnitus, urticaria, vomiting and weight increased. The patient was treated at hospital on 07-MAY-2007, 09-MAY-2007, 26-OCT-2007, 09-DEC-2007, 05-FEB-2008, 12-MAR-2008, 16-APR-2008, 17-APR-2008, 08-MAY-2008, 19-OCT-2008, 18-NOV-2008, 01-APR-2009, 18-MAY-2009, 27-MAY-2009, 28-MAY-2009 through 31-MAY-2009, on 03-SEP-2009, on 17-SEP-2009, on 20-SEP-2009, on 23-SEP-2009, on 19-OCT-2009, 23-OCT-2009, on 26-OCT-2009 through 28-OCT-2009, 17-NOV-2009, 23-NOV-2009, 24-NOV-2009, 14-DEC-2009 and 25-DEC-2009 for medical issues relating to adverse reaction to the GARDASIL. She was also treated at other hospital by multiple physicians on the fo

Other Meds: Albuterol; clonidine 0.1 mg; LEVOXYL

Lab Data: abdominal computed, 06/??/09, and pelvis: within normal limits

History: Bipolar disorder; Asthma; Anxiety; Behaviour disorder; Tic; Fibromyalgia; Hypersensitivity

Prex Illness: Convulsion; Influenza; Hypothyroidism; Depression; Hypersensitivity; Excessive eye blinking

Prex Vax Illns:

Vaers Id: **376090-2 (S)** **Related reports:** 376090-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Jan-2010	04-Jan-2010	0	23-Apr-2010	26-Apr-2010	--	WAES1004USA00990	26-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1109Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1013Y	1	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1257Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Cough, Dizziness, Dry mouth, Dyspnoea, Flushing, Heart rate increased, Injection site urticaria, Urticaria, Wheezing

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Act concerning a 17 year old female with congenital hydrocephalus and a medical history of 32 week preemie and Vascular shunt who on 04-JAN-2010 was vaccinated intramuscularly into the left arm with a second dose of GARDASIL (lot # 662304/1013Y). Secondary suspect vaccination included second doses of VAQTA, (lot # 665702/1257Y), intramuscularly into the right arm and VARIVAX (Merck) (lot # 665208/1109Y), subcutaneously into the left arm. No concomitant therapy reported. On 04-JAN-2010 the patient experienced cough, dizziness, dry mouth, dyspnoea, flushing, heart rate increased, urticaria and wheezing. The patient became flushed, she complained of difficulty breathing, wheezing and developed hives on trunk and extremities required prolonged observation at physician's office. The patient was given 0.5 mL (1:1,000) epinephrine subcutaneous, BENADRYL 50 mg oral, ORAPRED 60 mg x1 dose. Medical records received from 04-JAN-2010 to 11-JAN-2010 indicated that after vaccination the patient complained of flushing face, dizziness, cough and started to complained of SOB, also experienced wheezing, dry mouth. Then the patient had hives at injection site. Assessment: Chest clear, normal voice (+) hives, HR increased, EPI PEN gave, hives decreased, lungs clear, VSS hives gone, the patient was sent home in stable condition. The listing indicated that one or more of the events was considered to be immediately life-threatening. A lot check has been initiated. The original reporting source was not reported. The VAERS ID number is: 376090-1. A preliminary lot check investigation was performed. To date our investigation has found that the lot 665702/1257Y conformed to quality release parameters and the manufacturing was typical of a lot of VAQTA. Additional information will be provided upon finalization of this manufacturing investigation. A standard lot check investigation has been finalized. All in-process quality checks for the

Other Meds: Unknown

Lab Data: Unknown

History: Premature baby 26 to 32 weeks; Vascular shunt

Prex Illness: Congenital hydrocephalus

Prex Vax Illns:

Vaers Id: **378361-2 (S)** **Related reports:** 378361-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Aug-2009	09-Sep-2009	9	28-Apr-2010	29-Apr-2010	--	WAES1004USA01200	29-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abscess drainage, Blood test, Chest pain, Computerised tomogram, Condition aggravated, Conversion disorder, Convulsion, Cyanosis, Electrocardiogram, Electroencephalogram, Gaze palsy, Head injury, Hypoaesthesia facial, Hypoaesthesia oral, Incisional drainage, Incontinence, Iron deficiency anaemia, Loss of consciousness, Neurological examination, Nuclear magnetic resonance imaging, Paralysis, Respiratory arrest, Rhinoplasty, Subcutaneous abscess, Tremor, Trismus, Vision blurred

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 14 year old female patient was vaccinated with the first dose of GARDASIL (left arm, lot # 659054/0315Y). The vaccination date for GARDASIL was reported to be 31-AUG-2009. On an unspecified date, the patient sustained a head injury (was struck by a softball). The reported onset date for rhinoplasty was 06-AUG-2009. The reported onset date for convulsion was 08-AUG-2009 ("2 days status post rhinoplasty"). On 09-SEP-2009, the patient experienced a seizure like activity that lasted 20 minutes and she was taken home from school. On 14-SEP-2009, the patient experienced seizure like activity that lasted 40 minutes and she was taken by squad to ER and it was found that hemaglobins were 8.0 and at that moment she had severe iron deficiency anemia and was released. On 21-SEP-2009, the patient experienced chest pain an ER visit was released. On 22-SEP-2009, the patient experienced seizure like activity for 2 hours, she was squad to ER and was admitted for 4 days. On 01-OCT-2009, the patient experienced seizure like activity that lasted 2 and a half hour, she was squad to ER and was admitted for 3 days, the patient complained of blurry vision, body shaking, jaw clenching, incontinence, eyes rolled back, Loss of Consciousness, cyanosis, tongue and facial numbness. On 02-OCT-2009, the patient experienced seizure like activity that lasted 45 minutes while she was in the hospital. On 28-OCT-2009, the patient experienced seizure like activity that lasted 3 hours and she was taken home. On 27-DEC-2009, the patient experienced seizure like activity and she had trouble breathing, an ER visiting was released. On 02-JAN-2010, the patient experienced seizure like activity and she stopped breathing. A cardiopulmonary resuscitation (CPR) was performed and the patient was paralyzed for 15 minutes, she was squad to ER and released. Cardiology felt seizures not cardiac related to hematology: the patient was

Other Meds: Unknown

Lab Data: diagnostic laboratory, 01/14/10, the ED records showed a final impression: pseudo-seizures/conversion disorder; diagnostic laboratory, 09/22/09, left axilla abscess; hemoglobin, 09/14/09, 8.0; urine iron test, 01/14/10, iron deficiency anem

History: Syncope vasovagal; Convulsion; Axillary abscess

Prex Illness: Pollen allergy; Tracheal disorder

Prex Vax Illns:

Vaers Id: **378882-2 (S)** **Related reports:** 378882-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	29-Dec-2009	10-Jan-2010	12	26-Apr-2010	27-Apr-2010	--	WAES1004USA01207	28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1332Y	3	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Cough, Dysphagia, Fatigue, Joint swelling, Movement disorder, Nausea, Oedema peripheral, Pain, Pain in extremity, Pharyngeal oedema, Rash, Rash erythematous, Rash macular, Skin lesion, Tenderness

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. It was reported that an 18 year old female patient with an unusual cough, almost asthmatic, that kind of took her breath away. This had started 3 weeks prior and a history of exercised induced asthma and kind of routine occurring sinusitis but not at the time the injections were started who on 29-DEC-2009 was vaccinated intramuscularly with the fourth dose of GARDASIL (Lot # 665607/1332Y). On 10-JAN-2010, the patient started noticing a rash on her lower legs around her ankles, kind of just little red dots. The rash kept spreading and getting worse with bigger red blotches all up and down her legs but most heavily concentrated on her lower legs and feet. So, on 15-JAN-2010 they went to the doctor about the rash, the coughing and an acheness. He didn't know what it was and did some blood work that they wouldn't find out about until Monday (this was Friday). On the evening of 17-JAN-2010, she had swollen up so bad on her lower legs and ankles that you couldn't see any of her ankle bones, etc. Also was saying that she could hardly swallow so the reporter was concerned that throat was swelling like the legs. So, the reporter took her to the emergency room. They did blood work but said nothing showed up. They started tossing out possible things like lupus and auto-immune disease. The reporter didn't think that she told the doctors there about her just having had the 3rd dose GARDASIL. They gave her 60 mg a day of prednisone for 4 days. Electronic records for 18-JAN-2010: DX: Skin rash Patient presented with c/o rash and worsening swelling of legs. The rash had a gradual onset and had started a week ago. Examination noted swelling and tenderness in bilateral lower legs. The rash was described as red slightly raised lesions, which did not blanch when touched. The patient was discharged home and given prescriptions for LORTAB. The patient was counseled to follow-up with PCP in 1-2 days as sy

Other Meds: PROAIR; ADVAIR; CONCERTA; SINGULAIR; EFFEXOR

Lab Data: WBC count, 02/01/10, 10.9 (WNL); hemoglobin, 02/01/10, 13.6 (WNL); hematocrit, 02/01/10, 39.0 (WNL); blood glucose, 02/01/10, 59 (L); serum aspartate, 02/01/10, 13 (L); total serum bilirubin, 02/01/10, 1.2 (H); red blood cell count, 02/02/1

History: Asthma exercise induced; Sinusitis recurrent

Prex Illness: Cough; Asthma; Breathlessness

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **379011-2** **Related reports:** 379011-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Nov-2008	Unknown		25-May-2010	25-May-2010	OH		31-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Confusional state, Disturbance in attention, Dyspnoea, Hypersensitivity, Hypoaesthesia, Muscle twitching, Skin papilloma, Syncope, Vision blurred

Symptom Text: Blurry vision, warts (not genital), twitches, numbness, memory loss, no concentration, confused, trouble breathing, fainting (daily), very allergic to citric acid-now-never before.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **379965-2 (S)** **Related reports:** 379965-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Aug-2009	09-Oct-2009	64	28-Jun-2010	29-Jun-2010	TX		29-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0225Y	1	Unknown	Unknown	
	TDAP	SANOFI PASTEUR	UF485BA		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2873AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abnormal behaviour, Bed rest, Convulsion, Fatigue, Headache, Paralysis, Syncope, Tic, Visual impairment

Symptom Text: Seizure, convulsion, behavior changes, vision problems, temporary paralysis, fatigue, headache, motor tics movement disorder, fainting spells - treated with medication, acupuncture, vitamin therapy, rest.

Other Meds: None

Lab Data: EEG; CAT scan; Chest x-ray; MRI Brain; Lumbar puncture; Multiple blood draw; Neurological assessment

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **380740-2 (D)** **Related reports:** 380740-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	25-Aug-2009	01-Oct-2009	37	26-Apr-2010	27-Apr-2010	--	WAES1004USA01097	28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Unknown	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	500673P		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Activities of daily living impaired, Condition aggravated, Convulsion, Decreased activity, Fall, Headache, Hypertension, Hypoaesthesia, Injury, Loss of consciousness, Loss of control of legs, Menstruation irregular, Oedema peripheral, Paraesthesia, Peripheral coldness, Sensory loss, Sudden unexplained death in epilepsy, Unresponsive to stimuli, Weight increased

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 13 year old female with seizure disorder that came on with her periods and a history of 36 1/2 weeks gestation and difficulties at birth. The patient had a service date on 14-AUG-2009 assessment: Frontal lobe seizures, the patient presented for follow-up visit due to recent increase in seizure activity. Significant weight gain, High blood pressure. On 25-AUG-2009 the patient was vaccinated with the first dose of GARDASIL (lot # 663452/0671Y) as well as the flu nasal spray (lot # 500673P). The patient's mother declined her the vaccination but her doctor ensured that it was safe. The patient's mother declined the same vaccination a year earlier at the downtown public health center. On 01-OCT-2009 the patient experienced convulsion, decreased activity, fall, headache, hypertension, hypoaesthesia, injury, loss of control of legs, menstruation irregular, oedema peripheral, paraesthesia, peripheral coldness, sensory loss and weight increased. The patient was getting ready for school and was standing by her closet, and all of a sudden she fell, she lost total control of her legs. She went to school and could not engage in any of the activities because of the numbness in her legs and the swelling of her foot. She also, started to get a really bad headache. Days later she woke up out of her sleep complaining of a severe headache, which usually she got if she had a seizure but she had not had a seizure this night. She continued to say that she had not feeling in her foot and tingling feeling in her leg. After the patient's mother examined her foot, she noticed that it was swollen. The next morning the doctor was called and made an appointment on 23-OCT-2009. During the month of October she had irregular periods. The patient had the following test: white blood cell count: 4.5, blood lymphocyte count: 44.3, blood monocyte count: 13.5, serum alanine aminotransferase test: 43. The patient never

Other Meds: KEPPRA; TRILEPTAL

Lab Data: WBC count, 10?/??/09, 4.5 k/mm; lymphocyte count, 10?/??/09, 44.3%; monocyte count, 10?/??/09, 13.5%; serum alanine, 10?/??/09, 43 U/L

History: Normal delivery; Enteral feeding

Prex Illness: Convulsion disorder

Prex Vax Illns:

Vaers Id: **381305-2 (D)** **Related reports:** 381305-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Jun-2007	12-Feb-2010	962	01-Sep-2010	02-Sep-2010	WI		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2324AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Autopsy, Death, Headache, Meningococcal infection, Nausea, Petechiae, Vomiting

Symptom Text: Headache, nausea/vomiting began evening of 2/12/2010. Patient found dead morning of 2/13/2010. Autopsy performed 2/14/2010 - meningococcal disease determined to be COD. Gram negative diplococci observed on brain stem area, petechial rash observed by pathologist.

Other Meds: Possibly on Lithium

Lab Data: Neisseria meningitidis serogroup C confirmed by PCR on brain stem tissue collected on 2/14/2010.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **383350-2 (S)** **Related reports:** 383350-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Jul-2009	31-Jul-2009	22	31-Mar-2010	01-Apr-2010	--	WAES1003USA03610	03-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
DTP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	1130X	0	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia, Juvenile arthritis, Mobility decreased, Sight disability

Symptom Text: Information has been received from a register nurse concerning a 12 year old female with no pertinent medical history and no known drug allergies who on 09-JUL-2009 was vaccinated IM into right deltoid with a first 0.5ml dose of GARDASIL (lot# 661953/1130X). Concomitant therapy included ADACEL, DTaP, MENACTRA, and HAVRIX. At the end of July 2009 or beginning of August 2008, the patient experienced numbness of the fingers and toes. Shortly after, the patient was diagnosed with juvenile rheumatoid arthritis sometime before school started. The patient was seeing an unspecified specialist through an office visit. At the time of the report, the patient had not recovered. Juvenile rheumatoid arthritis was considered to be disabling by the reporter because of affecting eye sight and mobility. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **383396-2** **Related reports:** 383396-1; 383396-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		13-Apr-2010	14-Apr-2010	--		23-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Partial seizures

Symptom Text: Patient developed partial left temporal lobe seizures in Jan 2010 after completing third GARDASIL in Dec 2008. MRI revealed single area of abnormal signal in right hemisphere white matter. Leg left temporal seizure activity. Unknown if vaccine causative or related. Vaccine administered by pediatrician.

Other Meds:

Lab Data: Onset of partial epilepsy beginning in Jan 2010. MRI brain single area of leuko encephlopathy

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **383396-3** **Related reports:** 383396-1; 383396-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Dec-2009	01-Jan-2010	14	10-May-2010	11-May-2010	--	WAES1004USA04279	11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500835P		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1013Y	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Deja vu

Symptom Text: Information has been received from a registered nurse concerning a female who on 08-JUL-2008 was vaccinated with first dose of GARDASIL (lot# 66398/0072Y valid for ROTATEQ). On 20-FEB-2009, patient was vaccinated with second dose of GARDASIL (lot# 661952/1129X) and on 18-DEC-2009, patient received a third dose of GARDASIL (lot# 662304/1013Y) and also H1N1 (cold adapted Ann Arbor master strain). No concomitant medications were reported. On 27-FEB-2010, patient went to ER with complaint of "deja vu type episodes", lasting anywhere from 30 seconds to a couple of minutes, intermittently since January 2010. On 27-FEB-2010 a CT of the head was normal. Patient was referred to a neurologist who diagnosed the patient with seizure disorder. Patient was placed on unspecified medications. At the time of reporting, the patient's seizure disorder persisted. It was reported that patient's status was "not disabling (other that the fact that patient cannot drive)". Seizure disorder was considered to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Computed axial, 02/27/10, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **383486-2** **Related reports:** 383486-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	M	30-Sep-2009	30-Sep-2009	0	23-Apr-2010	26-Apr-2010	VA		26-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X		Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Erythema, Fatigue, Flushing, Hypersensitivity, Oral allergy syndrome, Rash macular, Rash papular, Rash pruritic, Skin burning sensation, Swelling face, Urticaria

Symptom Text: Receive her first GARDASIL vaccination at 0930 on 9/30/2009. She reported history of sore throat, body aches, low grade fever, runny nose and non-specific malaise for approximately the three days preceding her vaccination for which she was using THERAFLU and throat lozenges. Symptoms had resolved by the time of vaccination. Approximately 20 minutes after receiving this shot while having her blood drawn, she noticed a small area of mildly pruritic red raised bumps (pimple size) on her left forearm. She returned to clinic and was prescribed diphenhydramine 25 mg. About 12 hours later (@2230 hr) her face (jaw line) was puffy with welts and flushed. She had scattered red rash to both arms (upper/lower). She denied any throat swelling or pain, tightness, difficulty breathing or swallowing. No lip edema, no itching. No joint/muscle pain. She took her first BENADRYL (unsure if 1 or 2 caps taken), climbed into hot bathtub of water and fell asleep. She awoke about 5 am (10 hrs after vaccination) still in the bathtub and noticed a scattered red blotchy rash to chest, abdomen, back, buttock, arms, and legs. She again denied any diff breathing, lip edema, chest pain, or dysphagia. The "hives" appeared red and flat and were not pruritic. She did c/o of feeling weak and tired, and of increased skin sensitivity/burning in area of hives. She denied any new detergents, soaps, deodorants, lotions, oils, hair products, etc. She denied any food allergies. She presented to local clinic, diagnosed with an "allergic reaction" and was treated with CYCLOCORT top lotion, oatmeal bath and prednisone (60 mg x 5d, 40 mg x 5d, 20 mg x5d). She only took one dose of BENADRYL and only 2 days of steroids before stopping as she saw no resolution of symptoms. She did note relief with CYCLOCORT and used x 2 weeks with full resolution of symptoms. She denied mucosal involvement at any time. The area of her rash remained hypopigmented with skin returning to normal color about 5 months later. The patient is known to be atopic. In March 2010 she was ev

Other Meds: None

Lab Data: No labs; 4/22/2010 Time Reaction/comments, PST (controls +/-) 1000 4x4/15x25//0x0/0x0; ID (control -) 1000 0x0/0x0; PST, yeast 1000 0x0/0x0; GARDASIL[2] PST, 1:1 (FS) 1000 0x0/0x0; ID 1:100 1015 0x0/0x0 - 1:10 1030 0x0/0x0

History: See HPI notes: seasonal allergies, hx allergy testing, hx scalp lesions/alopecia x 1 treated at clinic.

Prex Illness: Cold: see HPI note

Prex Vax Illns:

Vaers Id: **383806-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Oct-2008	21-Oct-2008	4	30-Mar-2010	30-Mar-2010	--		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenopia, Confusional state, Electroencephalogram normal, Encephalitis, Lumbar puncture, Muscular weakness, Sensation of heaviness

Symptom Text: Diagnosis: encephalitis Symptoms: confusion, possible seizure The following information was obtained through follow-up and/or provided by the government. 4/8/10 PCP records and consultation received for dates of service 10/7/08 TO 3/12/09 Dx: Post vaccination encephalitis. Pt. had an episode of legs feeling heavy and weak while running, noticed sx. returned on exertion of climbing stairs. Several days after second HPV vaccine pt. had an episode in class where her eyes were very heavy and difficult to open, all noises around her seemed to fade into the distance and her head tipped forward and she did not have control to lift it back up. Unable to write with right hand, although attempting to do so. Vaguely recalls two people taking her by the arms and helping walk to the nurses office. Very confused and not responding appropriately to questions. Confusion lasted another two days. Experiencing frequent HA's, feels weak, experiencing frequent nausea. Saw neurologist. MRI revealed a thalmic enhancing lesion. EEG nl. Pt. had a similar episode of eye heaviness and weakness without the confusion. Started on Keppra. A repeat MRI showed the lesion had significantly decreased in size, a LP was normal. 4/19/2010 Neuro consult initial visit for 10/28/2008, labs and dx studies, Dx Post vaccination encephalitis

Other Meds:

Lab Data: Brain MRI 10/30/2008 revealed a 1.1 cm enhancing lesion in the left thalamus. Spontaneous resolution of the enhancement and significant improvement of the abnormal T2 signal on subsequent MRIs. The following information was obtained through

History: The following information was obtained through follow-up and/or provided by the government. 4/8/10 PCP records and consultation received for dates of service 10/7/08 TO 3/12/09 Dx: Post vaccination encephalitis 4/19/2010 Neuro consult initial visit for 10/28/2008, labs and dx studies, Dx Post vaccination encephalitis PMH: None Allergies: NKDA

Prex Illness: The following information was obtained through follow-up and/or provided by the government. 4/8/10 PCP records and consultatio

Prex Vax Illns:

Vaers Id: **383895-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		31-Mar-2010	01-Apr-2010	--	WAES1003USA02442	01-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Deafness, Memory impairment, Reading disorder, Visual impairment

Symptom Text: Information has been received from letter to the editor published in a newspaper, concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (Lot number, route and site of administration not reported). Subsequently the patient developed hearing loss and visual problems which make it very hard for her to read and retain information, which was her stronger suit, according to her mother. The consumer felt that her daughter problems were due to therapy with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **383896-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Nov-2009	06-Nov-2009	0	31-Mar-2010	01-Apr-2010	FR	WAES1003USA03124	01-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ53460	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature decreased, Convulsion, Grand mal convulsion, Headache, Hypertension, Hypothermia, Loss of consciousness, No reaction on previous exposure to drug, Tonic clonic movements

Symptom Text: Case received from a consumer (patient's mother) linked to medical query 10/030. A 13 year old female patient had received a second dose of GARDASIL (Batch number NL16940, lot number NJ53460, site of administration not reported) via intramuscular route on 06-NOV-2009. On 06-NOV-2009, some minutes after the administration the patient experienced a strong headache with decrease in body temperature, loss of consciousness and convulsion with tonic-clonic movements. A nurse measured her blood pressure which was high but, a few minutes later, blood pressure was normal. The nurse also informed the patient's mother that she should contact the emergency if the patient had additional events; however, it was not necessary. The duration of the episode was unknown. The patient recovered spontaneously without hospitalization or other medical treatment. To be noted that the patient had history of asthma treated during 2 years, skin allergic reactions but no allergic reaction to other drugs. The patient received the first dose of GARDASIL which was well tolerated. For the moment, the patient's mother was considering not to administer the third dose but she would contact a physician. Headache, hypertension, hypothermia, loss of consciousness and tonic-clonic convulsion were considered other important medical events by the reporter. Other business partner numbers include: E2010-01775. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure measurement, 06Nov09, High; blood pressure measurement, 06Nov09, normal

History:

Prex Illness: Asthma; Allergic skin reaction

Prex Vax Illns:

Vaers Id: **383897-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	05-Mar-2010	05-Mar-2010	0	31-Mar-2010	01-Apr-2010	FR	WAES1003USA03845	01-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Injection site pruritus, Pruritus, Rash erythematous

Symptom Text: Information has been received from a health authority (Case n. 113752). A 20 year old female patient was vaccinated intramuscularly with a dose of GARDASIL into her left arm on 05-MAR-2010. On the same day, about 20 minutes post vaccination, she presented with intense itching starting at the injection site, extending to the entire left arm and then to the neck, back and abdomen with non urticarial red spots. The patient was treated with TRIMETON 0.8 ml, intramuscularly after which the itching did not subside but onset of cough. Emergencies were called. The outcome was recovered on 05-MAR-2010. HA only coded injection site itching and cough. The case is closed. The agency considered itching, cough, rash and injection site itching to be other important medical events. Other business partner numbers include E2010-01795. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **383908-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	30-Mar-2010	30-Mar-2010	0	31-Mar-2010	31-Mar-2010	MO		03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1498Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dysphagia, Nausea, Pyrexia, Vaccine positive rechallenge, Vomiting

Symptom Text: Mother reported that patient had some nausea and vomiting after second dose of vaccine but did not report it to the HD. After thirs dose, patient had nausea, vomiting, fever and chills. Mother called PCP and was told that it was possible vaccine reaction. Mother also called the hospital ER and spoke with a nurse last night regarding the reaction. Mother also reported that patient said she experienced some difficulty swallowing. Mother said that ER nurse told parent to administer Ibuprofen 800 mg. for fever.

Other Meds:

Lab Data:

History: Pt reported allergy to Vicodin

Prex Illness: None reported.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **383936-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Mar-2010	30-Mar-2010	0	31-Mar-2010	01-Apr-2010	IL		01-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Dyskinesia, Vertigo, Vomiting

Symptom Text: Immunization given. Patient td well. To waiting room. Approx 5 min later patient jerking. Noticed by mother. Lasted approx 10-15 sec. Nurse went to patient. Patient awoke not sure of where she was. Patient c/o vertigo. Vomited. Assisted to exam room B/P 92/60 P62 R16 recovered. Patient resting on bed. Does not recall injection or what. Observed patient for 60 min. Patient c/o feeling fine. B/P 90/60 P62. Home with mother in good condition.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **383993-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
-0.7	F	16-Feb-2009	16-Feb-2009	0	01-Apr-2010	02-Apr-2010	NC	WAES0904USA01023B1	04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	
	DTAP	UNKNOWN MANUFACTURER	A014A		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Congenital anomaly, Foetal disorder, Foetal growth retardation, Foetal heart rate abnormal, Gastroschisis, Premature baby, Tachycardia foetal

Symptom Text: Information has been received from medical record concerning a female baby whose 25 year old mother smokes and has no pre-existing allergies, birth defects or medical conditions, no illness at time of vaccination and no history of previous pregnancies was vaccinated on 16-FEB-2009 was vaccinated IM in her right deltoid with the first dose of GARDASIL vaccine. Concomitant vaccination received the same day included a dose of diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (lot # A014). The physician indicated that her mother was pregnant at time of vaccination but it was too early to detect it. Her LMP was 26-JAN-2009, her EDD was 09-NOV-2009. From 17-FEB-2009 to 03-MAR-2009, the patient's mother took on CHANTIX to quit smoking. On 04-MAR-2009, the patient's mother had a positive urine pregnancy test. Subsequently on 18-MAR-2009 and on 20-APR-2009, two ultrasounds were done respectively to verify dates and pregnancy viability, and confirmed that vaccination occurred around conception, her estimated conception date was 16-FEB-2009 (+)/- 1 week). On 21-OCT-2009 at 5:45 am the infant's mother experienced spontaneous rupture of membranes. Her labor was induced and the infant experienced intrauterine growth restriction, baseline fetal tachycardia, loss of fetal heart rate variability and fetal gastroschisis during labor and delivery which have been captured in WAES # 0904USA01203. Fetal gastroschitis is considered a congenital anomaly. Additional information has been requested.

Other Meds: CHANTIX

Lab Data: Ultrasound, 03/18/09, EDC 11/9 + 11/7 (S<D). Confirmed vaccination occurred around conception; ultrasound, 04/20/09, EDC 11/9 + 11/7 (S<D), Confirmed vaccination occurred around conception

History: Smoker

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **383994-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Feb-2009	18-Mar-2009	45	01-Apr-2010	02-Apr-2010	NJ	WAES1003USA03534	02-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse, for GARDASL, a Pregnancy Registry product, concerning a 17 year old female patient who in February 2009, was vaccinated with the first dose of GARDASIL (lot# not reported). The patient subsequently became pregnant. Date of LMP not reported. On 18-MAR-2009 the patient had an elective abortion. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. Upon internal review, elective abortion was considered to be an important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **383995-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		01-Apr-2010	02-Apr-2010	TX	WAES1003USA04020	02-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Information has been received from a physician concerning a 16 year old female patient with a history of seizures who on an unknown date was vaccinated with her first dose of GARDASIL (lot# not reported). The next day after vaccination the patient experienced a seizure. It was reported that two to three days later the patient went to see a pediatrician, who told the patient to go back to the Ob-Gyn physician and let him know about the seizure. It was noted that the patient did have a history of seizures but had not had any seizures for a while until the day after vaccination with GARDASIL. No further seizures were noted since the seizure the day after receiving GARDASIL. At the time of the report, the outcome of the patient was unknown. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384000-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	25-Mar-2010	26-Mar-2010	1	01-Apr-2010	01-Apr-2010	PA		01-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling, Lip swelling, Pharyngeal oedema, Swelling face

Symptom Text: Client reported adverse event to us on 03-31-10 in the pm via the State Health Center answering machine. In follow up on 4-1-10: The Client received her GARDASIL (HPV) vaccine @ approximately 1 pm on 3-25-10. Client states she felt "fine the rest of the day and evening." and went to spend the night at a friend's house (on 03/25/1020). She reports waking up at 1 AM on 3-26-10 with the following symptoms: right-sided swollen lip, cheek and eye, and a swollen throat. At approximately 4 a.m. she states she took x4 "over-the-counter" Benadryl tablets and by approximately 6 to 7 AM on 3-26-10 the swelling "started going down". At 11 A.M. on 4-1-10 client states "I feel perfectly fine now."

Other Meds:

Lab Data:

History: Allergies: Penicillin and Sulfa Drugs. Grass, trees, mold, ragweed, goldenrod and animals.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384002-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Mar-2010	30-Mar-2010	0	01-Apr-2010	02-Apr-2010	WA		02-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3021AA		Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B0Y3BA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1538Y		Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0249Y		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Patient had episode syncope in waiting room. Hit head against chair. Recovered easily. Improved with rest in swinging position. BP HR stable.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384030-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	27-Jan-2010	03-Feb-2010	7	01-Apr-2010	02-Apr-2010	VA		04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Injection site haematoma, Injection site pain, Loss of proprioception

Symptom Text: Trouble with proprioception both arms felt "disconnected." like they wanted to fall off for 3 days. Experienced pain at injection site thru mid-Feb. Then tapered off in late February. Bruise at injection site that lasted a long time.

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384093-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-Mar-2010	29-Mar-2010	0	02-Apr-2010	02-Apr-2010	ME		14-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diet refusal, Dizziness postural, Fatigue, Feeling hot, Pallor

Symptom Text: Pale today (3/30/10), feels hot when she stands up and very dizzy on 3/30/10. She had a busy weekend and she is tired. Didn't eat last night and went to bed at 6 pm.

Other Meds: None

Lab Data: None

History: None

Prex Illness: Possible viral

Prex Vax Illns:

Vaers Id: **384103-1** **Related reports:** 384103-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Apr-2010	05-Apr-2010	--	WAES1003USA04275	05-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Multiple sclerosis

Symptom Text: Information has been reported in a published article concerning a young women who were vaccinated with a dose of GARDASIL and approximately 1 month later presented to clinics with a demyelinating syndrome that subsequently met criteria for multiple sclerosis. At the time of report the outcome was unknown. The reporter felt that aggressive acute disseminated encephalomyelitis was related to therapy with GARDASIL. Upon internal review, multiple sclerosis was determined to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **384103-2** **Related reports:** 384103-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Apr-2010	05-Apr-2010	--	WAES1003USA04558	28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Multiple sclerosis

Symptom Text: Information has been reported in a published article concerning a young women who were vaccinated with a dose of GARDASIL and approximately 1 month later presented to clinics with a demyclinating syndrome that subsequently met criteria for multiple sclerosis. At the time of report the outcome was unknown. The reporter felt that aggressive acute disseminated encephalomyelitis was related to therapy with GARDASIL. Upon internal review, multiple sclerosis was determined to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **384106-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	11-Aug-2009	11-Aug-2009	0	02-Apr-2010	05-Apr-2010	GA	WAES0908USA01918	05-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aborted pregnancy, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for GARDASIL, a pregnancy registry product, concerning a 24 year old female with no pertinent medical history and no drug reactions/allergies who was vaccinated in June 2008 and on 11-AUG-2009 with a dose of GARDASIL. There was no concomitant medication. On 11-AUG-2009, the patient had a positive urine pregnancy test. The estimated gestational age at the time of this reporting was four weeks. The last menstruation period was approximately 12-JUL-2009 and the estimated delivery date would be approximately 18-APR-2010. The patient had sought unknown medical attention. At the time of report the patient's status was unknown. Follow-up information has been received concerning a female patient with no significant past medical history and one elective termination who in June 2008 was vaccinated with the first dose of GARDASIL somewhere else and on 11-AUG-2009 was vaccinated with the second 0.5 ml dose of GARDASIL (Lot# 659655/0940X). There were no concomitant therapies. On 21-AUG-2009 ultrasound was performed which revealed that the dating was 6 2/7 weeks. On 31-AUG-2009 the patient signed the consent form for the Merck registry for GARDASIL. Follow-up information has been received indicated that the patient aborted her pregnancy due to personal reasons. Upon internal review, the aborted pregnancy was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, 08/21/09, 6 2/7 week - dating; urine beta-human, 08/11/09, positive

History: Termination of pregnancy - elective

Prex Illness:

Prex Vax Illns:

Vaers Id: **384108-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	05-Jan-2010	05-Jan-2010	0	02-Apr-2010	05-Apr-2010	NE	WAES1003USA04208	05-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0669Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hemiplegia, Hypoaesthesia, Immediate post-injection reaction

Symptom Text: Initial and follow-up information has been received from a Licensed Practical Nurse concerning a 20 year old female with no pertinent medical history and no drug allergies who on 05-JAN-2010 was vaccinated intramuscularly in right deltoid arm with the first 0.5 mL dose of GARDASIL (LOT# 0669Y). Concomitant therapy included DEPO-PROVERA. The patient felt numbness from head to toe right after receiving the vaccine. There was no lab diagnostic study performed. She recovered few minutes later. On 29-MAR-2010, a voice mail message was received from the nurse. It was reported that the patient received no other vaccines at the time of the GARDASIL vaccination. The nurse said that according to the patient directly after receiving the first dose, the patient was paralyzed on the right side for one minute. Even though medical staff was available, the patient did not tell them of this event. Therefore no treatment was given and no referrals were made. It wasn't until the patient came in for the second dose did the staff learn of the incident. The second dose of GARDASIL was not given. Upon internal review, paralyzed on the right side for one minute was determined to be an other important medical event. No further information is available.

Other Meds: DEPO-PROVERA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 384109-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Feb-2008	16-Feb-2009	356	02-Apr-2010	05-Apr-2010	--	WAES1003USA04309	17-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Asthenia, Atrioventricular block second degree, Autoimmune hepatitis, Gallbladder enlargement, Hepatic cirrhosis, Jaundice, Liver transplant, Oedema peripheral, Renal failure, Waist circumference increased

Symptom Text: Information has been received from a company representative who overheard a physician mention information concerning a patient who on an unknown date was vaccinated with a dose of GARDASIL (route, dose and lot number not provided). On an unknown date, the patient experienced "transverse mellitus" after getting GARDASIL which resulted in autoimmune hepatitis, which led to renal failure and liver transplant. The patient's outcome was unknown at the time of reporting. Upon internal review, myelitis transverse was considered to be an other important medical event. Attempts are being made to verify the existence of an identifiable patient and reporter. This is one of two reports from the same source. The following information was obtained through follow-up and/or provided by the government. 07/12/10. DC summary for 02/16/09-02/20/09. Pt p/w bilateral LE edema. Liver function tests elevated, eye color changed to yellow, increased abdominal girth, weakness. CT of abdomen showed mild bilateral ductal dilation and gallbladder thickening. ECG showed second degree heart block. Liver biopsy indicated cirrhosis. DX: Cirrhosis likely secondary to autoimmune disease. Tx: ADEK, spironolactone, prednisone. 07/12/10. Consult on 03/11/09. Pt p/w joint pain in knees, ankles and wrists. Physical was exam wnl. UA showed trace protein. Pt to decrease dose of spironolactone. Tx: 6-MP. Assessment: autoimmune hepatitis. Pt was doing better. ```Review of medical records does not support the diagnosis of tranverse myelitis.

Other Meds: Unknown

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: CT of abdomen and chest: abnormal. PT 20 sec and PTT 37 sec increased, ANA elevated. SGPT 222 IU/L (H), total bilirubin

History: Unknown The following information was obtained through follow-up and/or provided by the government. PMH and allergies none.

Prex Illness:

Prex Vax Illns:

Vaers Id: **384111-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		02-Apr-2010	05-Apr-2010	WI	WAES1003USA04340	05-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on an unspecified date was vaccinated with the second 0.5 ml dose of GARDASIL. Concomitant therapy included "SSRI". It was reported that the patient had a known history of seizures however had been off her seizure medications since she was 8 years old. Subsequently, on an unknown date the patient experienced two seizures. The patient sought unspecified medical attention. At the time of the report, the patient's outcome was unknown. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Convulsion disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: **384112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		02-Apr-2010	05-Apr-2010	--	WAES1003USA04562	06-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a Physician's Assistant concerning a 16 year old female patient who on an unspecified dates was vaccinated with all three doses of GARDASIL. Three months later the patient experienced seizures. At the time of the report the patient's outcome was unknown. The patient sought unspecified medical attention. Upon internal review seizures was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384117-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Mar-2010	26-Mar-2010	0	02-Apr-2010	05-Apr-2010	FR	WAES1003TWN00019	05-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a health professional concerning a 14 year old female who on 26-MAR-2010 was vaccinated with GARDASIL. On 26-MAR-2010 the patient experienced mouth convulsion and was hospitalized. The reporter felt that mouth convulsion was related to therapy with GARDASIL. On 27-MAR-2010, information has been received from a physician of Hospital. The patient's situation was similar to that of 26-MAR-2010 and the vital signs were stable. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **384134-1** **Related reports:** 384134-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Feb-2009	Unknown		02-Apr-2010	02-Apr-2010	IL		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Decreased appetite, Glucose urine, Glycosylated haemoglobin increased, Hypothyroidism, Limb injury, Nocturia, Polydipsia, Polyuria, Rash pustular, Type 1 diabetes mellitus, Urine ketone body present

Symptom Text: Pt diagnosed with insulin dependant diabetes 7/13/09. Received GARDASIL 6/6/08, 8/8/08, & 1/2/09. Younger sister recently diagnosed with IDDM and parent questioning possible role of vaccine. Pt also subsequently diagnosed with hypothyroidism. The following information was obtained through follow-up and/or provided by the government. 4/6/10 Medical records received for dates of service 5/07/09 to 3/24/10. Dx: Type 1 Diabetes Melitus. Finger sprain, foot injury, pustules. Hypothyroidism. Presents with 4 wk. hx. of polyuria and polydipsia (excessive drinking and has to urinate more frequently, waking to use the bathroom 2-3 times a night). Decreased appetite. Mucous membranes slightly dry. Urine with glucose and ketones. Hemoglobin A1C elevated. New onset Type 1 DM. Admitted for diabetic education and stabilization. Started on Lantis and Novalog. Dietary teaching completed. Pt. did well, managed insulin well. Discharged to home.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 4/6/10 Medical records received for dates of service 5/07/09 to 3/24/10. Labs and diagnostics: Glucose 295 (H), Chloride 95 (L), Sodium 133 (L),

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **384135-1** **Related reports:** 384135-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Feb-2010	29-Mar-2010	42	02-Apr-2010	02-Apr-2010	IL		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1317Y	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood glucose abnormal, Conversion disorder, Glucose urine, Hyperglycaemia, Joint injury, Nocturia, Polydipsia, Polyuria, Sick relative, Type 1 diabetes mellitus, Underweight

Symptom Text: Patient received GARDASIL vaccine 8/5/09, 12/12/09 and 2/15/10. Pt diagnosed with type 1 diabetes on 3/29/10. Sister also with IDDM (Vaers Filled out) Parents Questioning Role of vaccine. The following information was obtained through follow-up and/or provided by the government. 4/6/10 Primary care and hospital records received for dates of service 2/10/09 to 3/29/10. Dx: Underweight, Disorder ulna / radius / wrist joint, Somatic overinvolvement, low grade hysteria, hyperglycemia, new onset Type 1 Diabetes Melitus. Presents with 2-3 week hx. of polyuria and polydipsia, otherwise feeling well. Pts. mother noted that she has been waking several times in the night over the past few weeks to use the restroom. Older sister dx. last fall with new onset DM, so mom had her check pts. accucheck before eating which was 244 prior to eating. Pt. had urine dip done at home which showed 0 ketones, but did have "small" glucose. Admitted for diabetic teaching and monitoring. Started on Novolog.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 4/6/10 Primary care and hospital records received for dates of service 2/10/09 to 3/29/10.Labs and diagnostics: Glucose 430 (H), HGB A1C 10 (H).

History: None

Prex Illness: None

Prex Vax Illns: diabetes~HPV (Gardasil)~UN~15.00~Sibling

Vaers Id: **384170-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Mar-2010	23-Mar-2010	0	02-Apr-2010	05-Apr-2010	OH		05-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: Complains of arm pain and swelling at injection site. Symptoms continued for at least 10 days. Patient noted significant swelling 8 days post vaccination. Seen in office on day 10. Normal exam. No rash, swelling noted. Able to perform ADLS independently. Good ROM on exam. Treated with ibuprofen in office.

Other Meds: Micronor

Lab Data: Not done

History: rash - possible vitiligo, referred to Dermatology

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384173-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Apr-2010	02-Apr-2010	0	02-Apr-2010	05-Apr-2010	CA		05-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3438AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3081AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor

Symptom Text: Patient became light-headed and pale. Patient was placed in shock postition on exam table, ice-pack to base of neck. Patient stated no breakfast and no liquid intake yet this AM. Given approx 300cc's water and piece hard candy. after 15 to 20 minutes symptoms resolved.

Other Meds:

Lab Data: N/A

History: N/A

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384180-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Apr-2010	01-Apr-2010	0	03-Apr-2010	05-Apr-2010	CA		05-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	9670403	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Hypotension, Peripheral coldness, Syncope

Symptom Text: fainting, sweating and cold at extremities, hypotension

Other Meds: none

Lab Data: no

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384181-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	26-Mar-2010	26-Mar-2010	0	03-Apr-2010	05-Apr-2010	VA		05-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depressed mood, Influenza like illness, Malaise, Pyrexia, Vertigo

Symptom Text: Slight fever; general malaise; vertigo; flu-like symptoms; depression of mood

Other Meds: Venlafaxine 100mg

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384182-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Mar-2010	04-Apr-2010	8	04-Apr-2010	05-Apr-2010	OH		06-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cardiac flutter, Dizziness, Tremor

Symptom Text: Dizziness, lightheaded, heart fluttering, tremors

Other Meds:

Lab Data:

History: no, healthy athletic 15 year old c no previous health history

Prex Illness: 3rd shot of series c no initial reactions

Prex Vax Illns:

Vaers Id: **384204-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		05-Apr-2010	06-Apr-2010	FR	WAES1003USA04754	06-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Monoplegia, No reaction on previous exposure to drug

Symptom Text: Case received from Health Care Professional in a foreign country on 18-MAR-2010. AE received and collected in a survey conducted to identify the pattern of use of HPV vaccine made from phone call interview with users. Results of the survey were provided as a table with patient identification and AE experienced after each dose, if any. There were 4 categories of adverse reactions in which several AEs may be listed into parenthesis without specifying if the patient had experienced only one AE or all of them. A 23 year old female patient had received on unspecified date a first dose of GARDASIL (batch n., site of administration and route not reported). On unspecified date, the patient presented with immobilized arm after the first dose. Outcome was unknown. On unspecified dates, the patient received a second and a third dose of which were well tolerated. File is closed. Upon internal review, monoplegia was considered to be an other important medical event. Other business partner numbers included E2010-01983.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **384205-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		05-Apr-2010	06-Apr-2010	--	WAES1003USA04772	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death, Headache, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse practitioner concerning a 13 year old female patient who on unspecified dates was vaccinated with three doses of GARDASIL at the nurse practitioner's previous practice. The patient experienced headache after getting first and second dose of GARDASIL. The patient sought unspecified medical attention. After the third dose of GARDASIL the patient experienced headache and died on the same day. The cause of death was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384235-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Aug-2009	10-Aug-2009	0	05-Apr-2010	05-Apr-2010	IA		05-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF471CA	5	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Feeling abnormal, Feeling cold, Skin discolouration, Tremor

Symptom Text: The evening after vaccine she was cool shaky gray, tired. They started to take her to ER, but she wanted to go home. She had been laying on the floor and "felt like she was going to die". By the time got to the ER felt better and went home. No fever HR ok.

Other Meds:

Lab Data: None done/

History: Allergies to Amoxcillin, Penicillin

Prex Illness:

Prex Vax Illns:

Vaers Id: 384247-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Mar-2010	28-Mar-2010	2	05-Apr-2010	06-Apr-2010	FL		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Areflexia, Asthenia, Back pain, CSF glucose increased, Constipation, Haemolytic anaemia, Headache, Hypoaesthesia, Hyponatraemia, Immunoglobulin therapy, Limb discomfort, Muscle spasms, Muscular weakness, Musculoskeletal discomfort, Myalgia, Myoglobinuria, Pain, Paraesthesia, Vision blurred, Vomiting, Walking aid user, Wheelchair user

Symptom Text: Body aches, feet numb progressing to weakness inability to walk - Lumbar puncture high protein no cells - previously Guillain Barre diagnosed at 5 years age - currently treated with IVIG and improving. The following information was obtained through follow-up and/or provided by the government. ED report received 04/06/10 for DOS 01/29/10. Pt c/o weakness, double vision, impaired speech. On 03/26/10, Pt c/o B eyes very red-possible pink eye. Pt seen again 03/30/10 and c/o HA, feet and hands numbness and tingling, aches of whole body, muscles, hips, and back. Neuro exam: DTR +1, muscle strength 5/5. The next day, Pt unable to walk, in pain, legs sore, back muscles cramps, arms sore. Assessment: muscle weakness. H&P and DC summary received 04/07/10 for DOS 04/01/10-04/15/10. DC DX: GBS, hemolytic anemia, status post IVIG, hyponatremia resolved, constipation resolving, myoglobulinuria. Pt p/w weakness, difficulty walking, frontal HA, progressive body weakness, emesis, low back pain, blurred vision. tx: NS, IVIG. Neuro exam: BLE strength 3/5, unsteady gait, unable to walk. DTR absent. Pt strength improved, but pt still unsteady, so Pt in wheelchair, walker. Pt did not transfer to rehab, because Pt received PT/OT for 2 wks while hospitalized. Pt continued therapy as an outpatient. 05/19/10. Hematology/oncology consult for DOS 04/19/10, 05/06/10, 05/11/10. Pt reported improved energy, appetite, Hgb lowered. Pt still in wheelchair. Assessment: hemolytic anemia. Tx: prednisone, onadnsetron. On 05/06/10, f/u visit. Anemia responding well to steroids.

Other Meds: None

Lab Data: CSF fluid increased protein no cells; confirming Guillain Barre The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: CO2 20 mmol/L (L), WBC 14.3 (H), CSF report: clear, no growth,

History: The following information was obtained through follow-up and/or provided by the government. PMH: GBS in 1999, URI 3 wks ago and gastroenteritis 2 wks ago. Allergies: none.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384271-1** **Related reports:** 384271-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Apr-2010	03-Apr-2010	1	05-Apr-2010	06-Apr-2010	MD		22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	4F451BA	5	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	13174	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort, Pain, Pain in extremity

Symptom Text: Aching legs during midnight mass, during night severe pain, Sunday some discomfort much milder. None on Monday.

Other Meds: none

Lab Data: none

History: mild allergy, asthema

Prex Illness: none

Prex Vax Illns:

Vaers Id: **384271-2** **Related reports:** 384271-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Apr-2010	04-Apr-2010	2	21-Apr-2010	21-Apr-2010	MD		22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1317Y	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	4F451BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Asthenia, Fatigue, Nausea, Pain, Pain in extremity

Symptom Text: Approx 36 hours after received 1st HPV and TDAP (had had 5 prior DTAP) pt had severe pain from waist down to feet. Pt then felt a somewhat tired and weak overall and laid in bed much of day but could walk normally. Then 48-72 hours after vaccines received, pt developed upper stomach ache and nausea. She was still somewhat tired but leg pain and weak feeling in legs resolved.

Other Meds:

Lab Data: None

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: **384286-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.2	M	13-May-2009	13-May-2009	0	06-Apr-2010	07-Apr-2010	--	WAES0906USA03411B1	04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received through the pregnancy registry for GARDASIL, from a registered nurse concerning a male baby who was born by C-section on 16-JAN-2010 and had maternal drug exposure to GARDASIL. On 13-MAY-2009, the patient's mother was vaccinated with her first dose of GADASIL (lot # 661953/1130X) (WAES # 0906USA03411). It was reported that on an unspecified date the baby was hospitalized; no other information was available regarding the baby event. At the time of the report the baby's outcome was not specified. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 384382-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Jul-2007	06-Nov-2008	486	06-Apr-2010	07-Apr-2010	WI		26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426F	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Anaemia, Colitis ulcerative, Diarrhoea haemorrhagic, Flank pain, Haematochezia, Hepatosplenomegaly, Nausea, Pyrexia, Underweight, Vomiting

Symptom Text: patient developed ulcerative colitis The following information was obtained through follow-up and/or provided by the government. 4/20/2010 MR and DC summary for 11/6-11/17/2008, Dx UC patient with c/o's bloody diarrhea, fever, nausea and abdominal cramping, tx: IV ABX and steroids, patient failed po steroids and sx returned, transferred to Mayo Clinic for continuing care. 8/9/10 Discharge summary received for dates of service 11/23/08 to 11/30/08. Dx: UC, Abdominal pain, acute, severe, Severely underweight. Presents with new onset LLQ pain with radiation to the left flank and vomiting. Admitted for monitoring and management. Placed NPO with IV fluids and Morphine PCA. Ceftriaxone initiated. Continued to have frequent nocturnal bloody stools. Sx improved dramatically. Diet advanced to 1400 cal/day low-residual diet. Discharged in stable condtion. 8/16/10 Discharge summary received for dates of service 11/17/08 to 11/22/08. Dx: Ulcerative Colitis. Transferred to facility with dx of UC responsive to IV Solu-medrol but resistant to treatment with oral prednisone. Solu-medrol successfully decreased blood in stools. frequency of bowel movements, and abdominal pain. Pt is anemic. Not having any pain with oral intake. Mild hepatosplenomegaly. Discharged on low residue diet.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 4/20/2010 MR and DC summary for 11/6-11/17/2008, Dx UC Labs: CBC: wbc and bands high, hgb low, stool +ob, stool +wbcs, stool cultures negative, P-

History: None The following information was obtained through follow-up and/or provided by the government. 4/20/2010 MR and DC summary for 11/6-11/17/2008, Dx UC PMH: S/P inguinal hernia repair 2007 Allergies: NKDA

Prex Illness: No The following information was obtained through follow-up and/or provided by the government. 4/20/2010 MR and DC summary for 1

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384431-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2010	01-Apr-2010	0	07-Apr-2010	07-Apr-2010	VA		07-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	M1354Y	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Loss of consciousness, Tonic clonic movements

Symptom Text: Dizzy, loss of consciousness x 30 seconds seizure - tonic clonic 30-60 sec. - oxygen provided and recovery vital signs monitored.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: 384475-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	18-Sep-2007	20-Jan-2008	124	07-Apr-2010	08-Apr-2010	CA		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061O	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal discomfort, Abdominal mass, Chills, Crohns disease, Dehydration, Diarrhoea, Dizziness, Gastrointestinal pain, Nausea, Pyrexia

Symptom Text: intestinal discomfort and pain, nausea, that increased episodically over time The following information was obtained through follow-up and/or provided by the government. 4/9, 4/13 and 4/15/2010, OB-GYN records from 7/2007-3/2010, MR and DC summary for 2/6-2/10/2008, Dx Acute Crohn's flare, Dehydration patient with c/o's RLQ abd pain, fever and chills, diarrhea and dizziness, seen In ER 1/25/08 and sent home on Pentasa but has returned with worsening pain, PE abdomen noted palpable mass RLQ, Tx: IV steroids, dc'd home on Pentasa and po prednisone

Other Meds: Enbrel

Lab Data: CT and MRI, blood tests The following information was obtained through follow-up and/or provided by the government. 4/9, 4/13 and 4/15/2010, OB-GYN records from 7/2007-3/2010, MR and DC summary for 2/6-2/10/2008, Dx Acute Crohn's flare, Deh

History: Spondyloarthropathy The following information was obtained through follow-up and/or provided by the government. 4/9, 4/13 and 4/15/2010, OB-GYN records from 7/2007-3/2010, MR and DC summary for 2/6-2/10/2008, Dx Acute Crohn's flare, Dehydration PMH: AS Allergies: NKDA

Prex Illness: none The following information was obtained through follow-up and/or provided by the government. 4/9, 4/13 and 4/15/2010, OB-GYN

Prex Vax Illns:

Vaers Id: **384650-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Feb-2010	10-Feb-2010	9	08-Apr-2010	08-Apr-2010	PA		08-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Feeling abnormal, Gingival pain, Glossodynia, Hypoaesthesia, Muscle fatigue, Oropharyngeal pain, Paraesthesia, Renal disorder

Symptom Text: I experienced severe fatigue and muscle fatigue, joint pain in shoulder, fingers, knees toes all on the injection side of my body. Also, numbness and tingling in arm and leg, kidney problems, brain fog, and severe sore throat with gum and tongue pain.

Other Meds:

Lab Data: Blood work done to test for disorders, all negative.

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **384663-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Feb-2010	09-Mar-2010	12	08-Apr-2010	08-Apr-2010	MD		08-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Pain in extremity

Symptom Text: Patient gives hx of bilateral arm pain and back pain. Rx ibuprofen 800 mg.

Other Meds:

Lab Data: Labs ordered

History: No

Prex Illness: None known

Prex Vax Illns:

Vaers Id: **384711-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Apr-2010	01-Apr-2010	0	08-Apr-2010	09-Apr-2010	FL	WAES1004USA00293	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAUB662AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	00154Y	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	03090AA		Left arm	Unknown	
	DTAP	SANOFI PASTEUR	3246BA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Immediate post-injection reaction, Nasopharyngitis, Otitis media, Syncope, Unresponsive to stimuli

Symptom Text: Information has been received from a medical assistant and a physician concerning a 22 year old female with no medical history or drug allergies who on 01-APR-2010 was vaccinated with the first dose of GARDASIL (lot # 661954/0075Y), 0.5ml, IM. Concomitant therapy included MENACTRA and HAVRIX. The medical assistant reported that on 01-APR-2010 the patient experienced a seizure within seconds after receiving GARDASIL. The patient was taken to an emergency room and was given intravenous fluid. However, when intravenous fluid was stopped, another seizure occurred and she fell to the floor. The patient recovered on 01-APR-2010 and went home. The physician confirmed that the patient fell on her head after receiving GARDASIL. The patient went to the emergency room and was given an IV. The IV was removed and the patient got up to leave and fell on the back of her head. The patient had syncope occur twice in a 24 hour period. The patient recovered on 01-APR-2010. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 4/12 and 4/21/2010 ED records for 4/1/2010 , Dx syncopal episode patient saw PCP 4/1/2010 for well child visit and vaccinations, also with c/o's cold sx, dx'd with OM, immediately after vaccination child became unresponsive for 10-15 seconds, sent to ED for evaluation

Other Meds:

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. 4/12 and 4/21/2010 ED records for 4/1/2010 , Dx syncopal episode Labs: CBC, CMP, UA, urine drug screen, serum HCG all wnl/negative Dx studie

History: Unknown The following information was obtained through follow-up and/or provided by the government. 4/12 and 4/21/2010 ED records for 4/1/2010 , Dx syncopal episode PMH: None Allergies: NKDA

Prex Illness: The following information was obtained through follow-up and/or provided by the government. 4/12 and 4/21/2010 ED records for

Prex Vax Illns:

Vaers Id: **384712-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Mar-2010	31-Mar-2010	0	08-Apr-2010	09-Apr-2010	FR	WAES1004USA00146	09-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1334X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic shock, Injection site pain

Symptom Text: Initial case was reported by a Health Care Professional. Upon internal review, the case was considered serious due to anaphylactic shock. It was reported that a 15 year old female on 31-MAR-2010 was vaccinated with GARDASIL (first dose, batch# NL30760, lot# 1334X, IM route in arm). HCP reported that the girl remained in waiting room after vaccination since she experienced pain localized to the injection site. Approximately one hour later, after leaving the hospital, she experienced anaphylactic shock. She was taken to the hospital where she was treated with BETAPRED and then remained for observation for a little while. During the winter season 2009/2010 the girl experienced meningitis and infectious mononucleosis (no details reported). At the time of the vaccination with GARDASIL, the girl was healthy. The outcome was unknown. Upon internal review, anaphylactic shock was considered to be an other important medical event. Other business partner numbers include E2010-02136. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Infectious mononucleosis; Meningitis

Prex Illness:

Prex Vax Illns:

Vaers Id: **384713-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Mar-2010	05-Mar-2010	0	08-Apr-2010	09-Apr-2010	FR	WAES1004USA00144	09-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Joint hyperextension, Loss of consciousness, Post-traumatic amnestic disorder, Somnolence, Urinary incontinence

Symptom Text: Information has been received from a Health Authority under the reference number N201003-1133 on 29-MAR-2010 concerning a 13 year old female who had received a dose of GARDASIL (batch#, site of administration not reported) via intramuscular route on 05-MAR-2010. On the same day, five minutes post vaccination, she experienced convulsion with loss of consciousness, limb hyperextension and urinary incontinence. The patient recovered 20 minutes later but presented with somnolence and post-traumatic amnesia. Analytical study unchanged, research on toxics in urine negative and EKG without significant alterations. The patient was discharged with a diagnosis of favorable first seizure and send to pediatric neurology care for research. Previous adverse reactions to any drug are unknown. The patient completely recovered. Convulsion, loss of consciousness, limb hyperextension, urinary incontinence, somnolence and post-traumatic amnesia were considered to be other important medical events. Other business partner numbers included: E2010-02089. No further information is available. File is closed.

Other Meds: Unknown

Lab Data: electrocardiogram, negative, without significant alterations; urinalysis, negative, research on toxics in urine negative.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **384714-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Mar-2009	01-Apr-2009	31	08-Apr-2010	09-Apr-2010	OH	WAES1003USA04893	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea, Arthralgia, Blindness unilateral, Headache, Migraine, Nausea, Neurological examination normal, Optic neuritis, Photophobia, Vision blurred

Symptom Text: Initial and follow-up information has been received from a 21 year old female office worker concerning herself who in March 2009, was vaccinated with the first 0.5 mL dose of GARDASIL (LOT# not reported). On 01-APR-2009 the patient woke up and had loss of vision in her right eye. At this time of reporting, the patient's loss of vision had not recovered. Upon internal review, loss of vision was determined to be an other important medical event. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 4/12, 4/14, 4/16 and 4/19/2010 Neuro consult/MR for 9/14/2009, 1/26/2010, OB-GYN records for 7/2009-4/2010, Opthalmology ov 1/12/2010, Dx Ocular migraine patient evaluated for c/o's sudden onset visual disturbance rt eye with associated headache, seen in ED 3/31, dx studies were wnl, patient was then evaluated per a neuroopthalmologist who suspected optic neuritis, patient was tx'd with steroids with no resolution of sx, patient has hx of headaches with nausea and photophobia, the frequency of these headaches have increased, neurological exam wnl, dx still ?, recommended f/up in 4 months with repeat MRI brain and visual field testing, f/up visit visual field testing had improved but now with c/o's joint pain OB records indicate patient with amenorrhea, per neurologist to DC BCP, seen for IUD placement 5/11/2010 ED records for 3/31/2009, Dx Ocular migraine seen for c/o's headache and blurred vision rt eye, sudden onset, opthalmology and neurolgy consulted, tx: IV Lithium with resolution of sx.

Other Meds: Unknown

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. 4/12, 4/14, 4/16 and 4/19/2010 Neuro consult/MR for 9/14/2009, 1/26/2010, OB-GYN records for 7/2009-4/2010, Opthalmology ov 1/12/2010 5/11

History: Unknown The following information was obtained through follow-up and/or provided by the government. 4/12, 4/14, 4/16 and 4/19/2010 Neuro consult/MR for 9/14/2009, 1/26/2010, OB-GYN records for 7/2009-4/2010, Opthalmology ov 1/12/2010 5/11/2010 ED records for 3/31/2009, Dx Ocular migraine PMH: Migraines, MVA 2008, low back pain Allergies: NKDA

Prex Illness: The following information was obtained through follow-up and/or provided by the government. 4/12, 4/14, 4/16 and 4/19/2010 Neu

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384715-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Feb-2010	15-Feb-2010	4	08-Apr-2010	09-Apr-2010	FR	WAES1003USA04820	09-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ28290		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema multiforme, Rash

Symptom Text: This case was initially reported SPMSD by a health care professional on 30-MAR-2010. This case concerns a 14 year old female patient. The patient received dose one of GARDASIL, batch number NK31480 (lot# NJ28290), on 11-FEB-2010. On 15-FEB-2010, four days post vaccination, the patient developed a rash. The patient was seen by an "out of hours" doctor who diagnosed erythema multiforme. Treatment was initiated with antihistamines. The patient's mother confirmed that the erythema multiforme had improved dramatically by the next day. The patient was travelling the next day and was well enough to travel. At the time reporting the patient was recovering. The reporter considered the case to be serious as it was medically significant. Other business partner number include E2010-02076. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **384716-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Feb-2009	01-Aug-2009	178	08-Apr-2010	09-Apr-2010	FL	WAES0907USA05695	09-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy Registry product, concerning a 13 year old female patient who was vaccinated with the first, second and third dose of GARDASIL separately on 17-NOV-2008, 04-FEB-2009 and 04-JUN-2009. The physician did not know the patient was pregnant until an appointment in July 2009. The patient had done urinary test to confirm pregnancy. It was found out at this time the patient was pregnant for 5 months. The patient's date of last menstrual period was approximately on 01-FEB-2009 and estimated delivery date is 08-NOV-2009. Follow up information has been received indicating the patient had an elective abortion in August 2009. Upon internal review, the patient's elective abortion was considered an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Urinalysis, confirmed pregnancy

History:

Prex Illness: Pregnancy NOS (LMP = 2/1/2009)

Prex Vax Illns:

Vaers Id: 384717-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Aug-2008	12-Aug-2008	0	08-Apr-2010	09-Apr-2010	KY	WAES0809USA02166	09-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for the Pregnancy Registry for HPV vaccine concerning a 15 year old female with no pertinent medical history who on 12-AUG-2008 was vaccinated with the first dose of GARDASIL and ADACEL. At the time of vaccination with GARDASIL the patient was pregnant. On 02-SEP-2008, the patient came to the gynecologist office for annual physical exam and because she was missed her period, a pelvic ultrasound was performed that revealed a pregnancy of 14 weeks and 2 days. The patient's LMP was 9-JUN-2008 and EDD 16-MAR-2009. No adverse event occurred. Additional information has been received from a nurse concerning the patient. The nurse reported that the patient had a Cesarean section on 13-MAR-2009 and delivered a normal baby with "no problems", who weighed 9lbs, 13 oz. The nurse could not confirm the indication for the Cesarean. "It was possible it was due to the baby's size, but the nurse can't say for sure". The patient came back to the office at 2 weeks and 4 weeks postpartum for incision checks, but did not return for her "regular 6 week postpartum visit". The patient's incision was doing fine at the time and she was recovering from her Cesarean section. Upon internal review, Cesarean section was considered to be an other important medical event. Additional information is not expected.

Other Meds:

Lab Data: Ultrasound, 09/02/08, pregnancy 14 weeks, 2 days

History:

Prex Illness: Pregnancy NOS (LMP = 6/9/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384749-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	31-Mar-2010	02-Apr-2010	2	08-Apr-2010	09-Apr-2010	NY		09-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Chills, Cough, Decreased appetite, Diarrhoea, Dyspnoea, Ear pain, Headache, Malaise, Nausea, Night sweats, Pain, Palpitations, Pyrexia, Toothache, Urticaria

Symptom Text: Symptoms: Fever, malaise, chills, night sweats, slight cough, some shortness of breath, palpitations, watery diarrhea, decreased appetite, nausea, toothache, earache, body aches, headache, weakness. Developed hives 4 days after those symptoms. Treatments used: Bedrest, tylenol, advil, pepto bismol, prednisone, cephalexin, halobetasol cream

Other Meds:

Lab Data:

History: gastritis

Prex Illness: none

Prex Vax Illns:

Vaers Id: **384807-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	01-Jan-2009	Unknown		09-Apr-2010	12-Apr-2010	FR	WAES0903USA01270B1	12-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pyelocaliectasis

Symptom Text: Case received from a child care worker through the Sanofi Pasteur MSD GARDASIL pregnancy registry on 13-NOV-2009. This case is linked with the case E2009-01419 (patient's mother). A male neonate whose mother had received the third dose of GARDASIL (batch number not reported) in January 2009 during pregnancy experienced left pyelocaliceal dilatation, as detected by prenatal ultrasound (date not reported). A renal ultrasound was performed three days after birth and showed normal right kidney and slight dilatation of the renal pelvis in the left kidney. One month after birth the ultrasound showed that dilation had diminished. The patient was born at 39 weeks. His mother had undergone epidural anaesthesia and the top of his head came first at delivery. The patient's birth weight was 3.570 kg and his birth size was 50.5 cm. His head circumference was 36 cm and he had an Apgar score of 10. The patient was reported to be normal without congenital anomaly. The patient was followed by a paediatrician. His growth was considered as normal. Upon internal review it was decided to code hepatitis B vaccine as concomitant because it was no more reported as suspect vaccine in the different questionnaire. Follow up information received by telephone on 11-MAR-2010. The paediatrician did not know the patient and might have difficulty in finding him. No further information expected. A corrective version was created on 08-APR-2010. Upon medical review, the company upgraded the case to serious: pyelocaliectasis was considered as congenital anomaly. It was noteworthy that the patient did not consider the event was a congenital anomaly. The mother's experience has been captured in WAES# 0903USA01270. Other business partner numbers include: E2009-11206.

Other Meds: hepatitis B vaccine, recomb

Lab Data: renal ultrasound, 13Aug09, Slight dilatation of the renal pelvis in the left kidney; renal ultrasound, 10?Sep09, dilation had diminished

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **384818-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Mar-2010	01-Mar-2010	0	09-Apr-2010	12-Apr-2010	CA	WAES1004USA00211	12-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy, Musculoskeletal stiffness

Symptom Text: Information has been received from a nurse concerning a female patient who "within the last month" received her was vaccinated a first dose of with GARDASIL (Lot# not reported). Nurse reported that the patient stiffened up, her eyes rolled towards the back of her head and "seemed to have a seizure". The nurse stated that it was different from syncope. The patient was fine afterwards. It was unknown if the patient sought medical attention. Upon internal review, "seemed to have a seizure " was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **384819-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Mar-2010	19-Mar-2010	0	09-Apr-2010	12-Apr-2010	FR	WAES1004USA00145	12-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ37720	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Pallor, Syncope

Symptom Text: Information has been received from a Health Authority (initial case was reported as serious on 30-MAR-2010, HA ref. NO-NOMAADVRE-FHI-2010-10260, FHI 10-859) concerning a 12 year old female who on 19-MAR-2010 was vaccinated with the first 0.5 mL dose of GARDASIL (LOT# NJ37720, batch # NK45870, parenteral route). HA coded convulsion, syncope, dizziness and pallor (causalities possible) with onset 8 hours post vaccination on 19-MAR-2010. The duration of convulsion and with onset 8 hours post vaccination on 19-MAR-2010. The duration of convulsion and syncope was 1 minute, whereas 30 minutes for dizziness and pallor. According to the report the girl was referred to further examinations (no details reported). The outcome was recovered. The Institute has asked for more information. Convulsion, syncope, dizziness and pallor were considered to be other important medical events. Other business partner numbers included: E2010-02113. No further information was available at time of reporting. File is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **384853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	02-Apr-2010	05-Apr-2010	3	09-Apr-2010	12-Apr-2010	OH		12-Apr-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0971Y	1	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	1099Y	1	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB349AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Rash, Urticaria

Symptom Text: Swollen at injection site at right deltoid muscle. Rash present with urticaria on right upper arm and right facial cheek.

Other Meds:

Lab Data:

History: Patient has history of allergic reaction to Amoxicillin ATB, causing hives/rash.

Prex Illness: None reported

Prex Vax Illns:

Vaers Id: **384880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-Dec-2008	29-Dec-2008	0	12-Apr-2010	12-Apr-2010	TX		12-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hair growth abnormal, Injection site pain

Symptom Text: She had severe pain at the injection site all 3 times, but she has also started growing a lite covering of hair on her back since these injections!

Other Meds: At the time, she was only taking 10 mg of Claritin daily.

Lab Data:

History: Allergic to sulfa-based antibiotics

Prex Illness: No.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384898-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	25-Mar-2010	25-Mar-2010	0	12-Apr-2010	12-Apr-2010	MO		12-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Patient was given vaccine, couple of minutes, then walked to check out desk. While waiting patient passed out. Patient was monitored for 30 min and released. Patient did not have any other reactions.

Other Meds:

Lab Data:

History: Arrhythmia

Prex Illness:

Prex Vax Illns:

Vaers Id: **384903-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	08-Apr-2010	08-Apr-2010	0	12-Apr-2010	12-Apr-2010	KY		12-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	2	Right arm	Unknown	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB140AA	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Fall, Pallor, Presyncope, Tremor

Symptom Text: Arms shaking, clammy skin, loss of color in face, vasovagal response no loss of consciousness. Slumped . Assisted to chair.

Other Meds: DEPO PROVERA

Lab Data: None

History: None Known

Prex Illness: "No"

Prex Vax Illns: 3/26/09~Hep B (no brand name)~2~19.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384963-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	M	26-Oct-2007	01-Feb-2008	98	13-Apr-2010	14-Apr-2010	FL	WAES0812USA01616B1	04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Congenital anomaly, Drug exposure during pregnancy, Duodenal atresia, Single functional kidney

Symptom Text: Information has been received from a physician and a consumer concerning her male baby, who in February 2008, was exposed through his mother to a dose of GARDASIL (lot number 659435/1265U) administered on 26-OCT-2007. Concomitant medication included (ORTHO TRI-CYCLEN). On 13-NOV-2008 the patient was born with a weight of 5 pounds/7 ounces and had anemia at birth. The infant was born with only one kidney and duodenal atresia which were considered congenital anomalies. In follow-up, the patient's mother mentioned that her "boy was born with a bunch of birth defects". The patient's outcome was unknown at the time of reporting. The mother's experiences were captured in WAES# 0812USA01616. The infant's experience was previously reported in WAES 0812USA01616. No further information is available.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384964-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Aug-2009	01-Dec-2009	120	13-Apr-2010	14-Apr-2010	FR	WAES1004USA00674	14-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ02680	1	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Amnesia, Dizziness, Muscle twitching, Muscular weakness, Nausea

Symptom Text: Information has been received from the agency via a Case Line Listing via CSL, as part of a business agreement, concerning a 17 year old female patient who on 03-AUG-2009, was vaccinated intramuscularly with her second 0.5 ml dose of GARDASIL (Lot# NJ02680, batch# NJ46520). It was reported that in December 2009, < 1 year, the patient experienced nausea (severe), faintness (severe), muscle weakness (severe), twitching (severe) and memory loss (severe). At the time of the report, the patient had not recovered. The reporting agency considered that nausea (severe), faintness (severe), muscle weakness (severe), twitching (severe) and memory loss (severe) were disabling events. The relationship between nausea (severe), faintness (severe), muscle weakness (severe), twitching (severe) and memory loss (severe) and vaccination with GARDASIL was unclassified. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384968-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Apr-2010	06-Apr-2010	0	13-Apr-2010	13-Apr-2010	NV		13-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	1	Right arm	Unknown	
	HEP	MERCK & CO. INC.	1023Y	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Syncope

Symptom Text: Patient fainted after administration of vaccine last for 30 second. No injury happen due to fainting after 30 second. Patient alert, oriented with mild headache x 2-3minute. BP=117/60 HR=78 RR=26 SO2=100%. Pt observed for 10 minute. Asymptomatic. Discharged.

Other Meds:

Lab Data: Vital sign monitored. No blood or lab ordered.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **384983-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		13-Apr-2010	14-Apr-2010	--		14-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Partial seizures

Symptom Text: Patient developed partial left temporal lobe seizures in Jan 2010 after completing third GARDASIL in Dec 2008. MRI revealed single area of abnormal signal in right hemisphere white matter. Leg left temporal seizure activity. Unknown if vaccine causative or related. Vaccine administered by pediatrician.

Other Meds:

Lab Data: Onset of partial epilepsy beginning in Jan 2010. MRI brain single area of leuko encephlopathy

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **385046-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Apr-2010	12-Apr-2010	0	14-Apr-2010	14-Apr-2010	TX		14-Apr-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0216Y	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3015AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1432Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Loss of consciousness, Pallor

Symptom Text: Client recieved her first HPV vaccine at the clinic and blacked out about 5-10 seconds after receipt of the vaccine. She complained of headache and was pale. We lay her on the ground, took her blood pressure (100/60) and gave her a snack since she had not eaten since breakfast. She recovered after about 10 minutes on the floor and I had her sit in a chair for 10 minutes before leaving with both parents.

Other Meds:

Lab Data:

History: none known

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385086-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	13-Apr-2010	14-Apr-2010	1	14-Apr-2010	15-Apr-2010	WA		15-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic, Urticaria

Symptom Text: 1-1 1/2 hours after receiving HPV #2 developed an itchy rash. Presented the following morning at health dept with extensive hive-like reaction, Rx'd BENADRYL 50 mg every 4-6 hours.

Other Meds:

Lab Data:

History: Hx of exercise induced asthma; eczema

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385088-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Feb-2010	05-Mar-2010	21	14-Apr-2010	15-Apr-2010	MA		15-Apr-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3018AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1233Y	1	Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037AA	5	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Henoch-Schonlein purpura

Symptom Text: Presented to ED 3/8/10, seen @ dermatology clinic 3/9/10 started on prednisone taper, triamcinolone cream, hydroxyzine, referral to nephrologist, cardiologist and dietician diagnosis of Henoch - Schonlein purpura.

Other Meds:

Lab Data: direct immunoflorescence shows IgA and C3 disposition in the vascular walls and superficial dermis (-) IgG, IgM and fibroin

History: obesity

Prex Illness: allergies vs possible early URI

Prex Vax Illns:

Vaers Id: **385095-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Mar-2010	30-Mar-2010	0	14-Apr-2010	15-Apr-2010	NH	WAES1004USA00925	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1206Y	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1013Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Clonus, Convulsion, Dizziness, Pallor, Posturing, Syncope

Symptom Text: Information has been received from a physician and a medical secretary, concerning a 15 year old female patient, with acne and allergy to AUGMENTIN and a history of anemia after a fractured femur in 2007, who on 30-MAR-2010 (also reported as "sometime last week"), was vaccinated with the first 0.5 mL dose of GARDASIL (route not provided) (lot number 662304/1013Y). Other vaccines administered the same day included VARIVAX (Merck) (dose and route not reported) (lot number 665576/1206Y). Other concomitant therapy included FINACEA and ZYRTEC. On 30-MAR-2010, (also reported as "sometime last week"), the patient experienced syncope with seizures (also reported as seizures-like activity) for less than 30 seconds. On 30-MAR-2010, the patient recovered. The patient sought unspecified medical attention. No referrals made. Upon internal review, seizure was considered to be an other important medical event. No further information is available. The following information was obtained through follow-up and/or provided by the government. 4/15/10 MR received for date 3/30/10. DX: wellness check CC: syncope with seizure after vax. pt given next dose of vax and had sycope episode again in MD office. Pt became pale, fainted and began having tonic posturing for 15 seconds. Remained pale and woozy x10 minutes.

Other Meds: FINACEA; ZYRTEC

Lab Data: Unknown

History: Anaemia; Femur fracture, Augmentin allergy

Prex Illness: Acne; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 385096-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Oct-2009	01-Nov-2009	12	14-Apr-2010	15-Apr-2010	NJ	WAES1004USA00620	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Arnold-Chiari malformation, Babesiosis, Back pain, Bone cyst, Burning sensation, Chest X-ray, Chest pain, Computerised tomogram, Deafness, Diplopia, Dysuria, Eye pain, Headache, Intervertebral disc disorder, Lumbar puncture, Muscular weakness, Nausea, Neck pain, Nuclear magnetic resonance imaging abnormal, Nuclear magnetic resonance imaging brain, Pain in extremity, Paraesthesia, Tinnitus, Urinary incontinence, Vision blurred, Vomiting, X-ray

Symptom Text: Information has been received from a physician concerning a 16 year old female with exercised induced asthma and ZITHROMAX allergies, who on 21-JUL-2009 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL (lot # 661953/1130X). The patient was vaccinated with a second dose of GARDASIL (lot # 663453/0249Y) on 20-OCT-2009. The patient developed back pain 2 weeks after receiving her second dose. The pain increased and spread to her head, neck, chest, abdomen and legs. She was also experiencing tingling and weakness of her legs, vomiting and difficulty urinating. The patient had not been able to attend school. The patient was hospitalized twice. The physician mentioned two diagnostic findings that have been ruled out as not significant: A syrinx on brain or spine MRI and a positive IGG titer for babesiosis from blood. The patient also had renal and abdominal ultrasounds, unspecified blood tests and an unspecified urologic testing. At the time of this report the patient had not recovered. Follow up information received from a physician indicated that the patient did not receive any concomitant vaccinations when she received the dose of GARDASIL. The patient started having symptoms approximately in November 2009. The physician stated that "so far all of the patient's tests have been negative" (tests unspecified). The patient's symptoms have been scattered. There was no diagnosis at this time. The physician stated that she had spoken to the patient's mother by phone on a daily basis. Follow up information received from a physician via medical records indicated that the patient was a female with mild urinary reflux and an Achilles tendon repair in 2006. The patient's mother had urinary system issues, a sacral nerve implant, and an ovariectomy done her father had asthma, allergies and disk problems, her brother had harlequin syndrome and her sister had severe allergies and asthma. On 20-OCT-2009 the patient was vaccinated intramuscularly with a second dose of GARDASIL (lot # 663453/0249Y). The patient devel

Other Meds: QUININE

Lab Data: serum immunoglobin G, positive for babesicsis The following information was obtained through follow-up and/or provided by the government. 4/15/10 Diag/Labs: CT abnormal, US(-), MRI(-), blood work(-). See box 7.

History: Tendon operation

Prex Illness: Syrinx; Chiari malformation; Intervertebral disc bulging; Drug hypersensitivity; Urinary tract disorder; Asthma exercise induced

Prex Vax Illns:

Vaers Id: **385097-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
-0.8	F	02-Mar-2009	12-Apr-2009	41	14-Apr-2010	15-Apr-2010	NY	WAES0906USA02107B1	15-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Congenital choroid plexus cyst, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 23 year old female who was vaccinated with the first dose of GARDASIL on 02-MAR-2009 and vaccinated with the second dose on 07-MAY-2009. There was no medical history. The reporter stated that the patient was now pregnant, and pregnancy was normal to date. The patient's last menstrual period was on 12-APR-2009 and estimated date of delivery was 17-JAN-2010. Her estimated date of conception was 20-APR-2009. A urine pregnancy test was performed. The patient had sought medical attention at the office. Follow up information has been received from the registered nurse concerning the patient with 2 previous pregnancies (1 full term delivery at 40 weeks and 1 elective termination), no birth defects in previous pregnancies, no infant complications in previous pregnancies and prenatal care (vitamins 1 tablet daily started on 06-MAY-2009) during pregnancy who delivered a male infant on 15-JAN-2010 (at 39 weeks). The infant was reported as normal with weight of 8 pounds 1 ounce and there were no complications or abnormalities. There were no infections or illnesses during pregnancy. On an unspecified date the patient had a positive sonogram of bilateral choroid plexus cyst and echogenic focus on the bowel. Follow up for genetic counseling "ie: Amino ml 46xx-AFP>ml." The mothers experience has been reported in 0906USA02107. Additional information is not expected.

Other Meds: vitamins (unspecified), tab

Lab Data: diagnostic laboratory, positive sonogram of bilateral choroid plexus cyst; diagnostic laboratory, positive sonogram of echogenic focus on the bowel

History:

Prex Illness: Prenatal care

Prex Vax Illns:

Vaers Id: **385112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	13-Apr-2010	13-Apr-2010	0	14-Apr-2010	15-Apr-2010	GA		15-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0821Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Dizziness

Symptom Text: Weakness, lightheadedness, arthralgias

Other Meds:

Lab Data: She is improving

History: None

Prex Illness: Soon after vaccine she noted fatigue, light headedness and arthralgias.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385114-1** **Related reports:** 385114-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Apr-2010	12-Apr-2010	0	14-Apr-2010	15-Apr-2010	OH		15-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Swelling face

Symptom Text: Patient returned to our office on 4/14/10 with complaints of swelling to her face and a rash on her neck that started after she got home the day she received the vaccine.

Other Meds:

Lab Data:

History: Septal Defect

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385137-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Apr-2009	22-Apr-2009	0	15-Apr-2010	15-Apr-2010	MI		15-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Headache, Oedema peripheral, Pain

Symptom Text: 2-3 hours after vaccination had swelling of arm and severe headache , crying in pain like sharp pain persistant for 1 day. No history of migraine or previous headaches

Other Meds:

Lab Data: None

History: no

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385151-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	09-Apr-2010	09-Apr-2010	0	15-Apr-2010	15-Apr-2010	KS		15-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	2	Left arm	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	027011	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Feeling hot, Headache, Pyrexia

Symptom Text: Received 2 immunizations at about 1045 4/9/10 - at about 1900 stomach upset, headache, fever 100 degrees. Feels hot all over. Reported this reaction 4/12/2010 with continued symptoms. No numbness or tingling.

Other Meds: Sprinter

Lab Data:

History: No Known allergies; No birth defects/med. cond

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385186-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Apr-2010	15-Apr-2010	1	15-Apr-2010	16-Apr-2010	AL		16-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3089AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1013Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U2963DA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	00962	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site pain, Nausea, Pyrexia

Symptom Text: Pt developed fever 104.8, nausea, headache, soreness at inj. site. Given MOTRIN - temp 102 degrees in office 4-15-10 815am checked - strep (-) - Pt will tx with TYLENOL/MOTRIN.

Other Meds:

Lab Data: Rapid strep (-)

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385197-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-Apr-2010	14-Apr-2010	1	15-Apr-2010	15-Apr-2010	MO		15-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	U3051AA	5	Right arm	Unknown	
	MEN	SANOFI PASTEUR	U3342AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	13774	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hallucination, Headache, Pyrexia

Symptom Text: fever 105 dizzy Headache Hallucinations

Other Meds: Concerta 18mg q am Singulair 5mg 1 tablet q day

Lab Data: none

History: Allergic Rhinitis, Asperger's Syndrome, ADHD/LD

Prex Illness: No

Prex Vax Illns:

Vaers Id: **385230-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	10-Nov-2008	Unknown		15-Apr-2010	16-Apr-2010	FR	WAES0907USA02109B1	16-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Atrioventricular septal defect, Drug exposure during pregnancy

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail for GARDASIL, a Pregnancy Registry product, concerning a baby. On 10-NOV-2008, the baby's 20 year old mother was vaccinated with a dose of GARDASIL. The baby's mother's concomitant therapy included ELEVIT RDI. The baby's mother had a positive home pregnancy test on 24-NOV-2008. On unspecified date the baby's atrioventricular septal defect was found on foetal morphology scan. Amniocentesis was to be performed. The event required a specialist consultation. At the time of the report, the baby's outcome was unknown. The reporter felt that atrioventricular septal defect was related to therapy with GARDASIL. The original reporting source was not provided. The mother's experience has been captured in WAES#0907USA02109. Additional information is not expected. The event of atrioventricular septal defect was previously reported in WAES0907USA02109.

Other Meds: ELEVIT

Lab Data: fetal monitoring tests, fetal morphology scan-Atrioventricular Septal Defect

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 385231-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	24-Mar-2010	24-Mar-2010	0	15-Apr-2010	16-Apr-2010	IN	WAES1004USA00622	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Pain, Pain in extremity

Symptom Text: Information has been received from a health care worker concerning a 23 year old female patient with anxiety disorder and penicillin allergy who on 29-JAN-2009, 27-JUL-2009 and 24-MAR-2010 received the first (intramuscularly), second and third dose of GARDASIL respectively (Lot # 662300/0100Y for third dose). Concomitant therapy included clonazepam, CYMBALTA and ORTHO TRI-CYCLEN. On 31-MAR-2010 the patient called the physician's office with arm pain. The physician recommended warm compression alternating with ice, and ibuprofen. The patient's pain did not improve, so she came to the office later that day. While in the office, the physician found "no redness and nothing visible". She complained of pain in the left arm radiating into the elbow, shoulder, and chest wall. The physician continued to recommend ice and heat along with naproxen and hydrocodone with acetaminophen. On 05-APR-2010, she was again seen in the office. The patient still had arm pain. She complained that she needed to sit with the arm supported. She stated that the pain was sharp with motion and radiated to the elbow and upper back. It caused her to miss a few days of work. The physician gave her prednisone and oxycodone with acetaminophen. At the time of this report, the patient was not recovered. The patient sought unspecified medical attention. The reporter considered the adverse events to be disabling and other important medical events. Additional information has been requested.

Other Meds: Clonazepam; CYMBALTA; ORTHO TRI-CYCLEN

Lab Data: None

History:

Prex Illness: Anxiety disorder; Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385232-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Apr-2010	16-Apr-2010	FR	WAES1004USA00701	16-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis, Nervous system disorder

Symptom Text: Information has been received from a journalist from a newspaper via CSL as part of a business agreement (manufacturer control # 20100406GCL), concerning a female patient with a family history of autoimmune disease who on an unspecified date was vaccinated with a dose of GARDASIL (route and lot # unknown). On an unspecified date, the patient suffered neurological attacks after receiving GARDASIL and at the time of the report the patient was taking medicine for MS like condition. It was reported that the patient had partly recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Familial risk factor

Prex Vax Illns:

Vaers Id: **385235-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	29-Mar-2010	29-Mar-2010	0	15-Apr-2010	16-Apr-2010	NJ	WAES1004USA01230	16-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Pruritus, Pyrexia, Rash generalised

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female with papanicolaou smear abnormal and papilloma viral infection positive (possibly for 16 and 18) and drug reactions or allergies reported as none who on 27-JAN-2010 was vaccinated with a first dose of GARDASIL (lot # 662299/1099Y) intramuscularly. There was no concomitant medication. It was reported that after first dose of vaccine she had no adverse effects. On 29-MAR-2010 she received second dose of GARDASIL (lot # not reported). On the same night as the second dose of vaccine on 29-MAR-2010, she developed a fever, itching and a generalized rash on the abdomen, arms and neck. The rash spread, so she reported to the office on 06-APR-2010. There was no fever when she reported to the office. The physician gave her a prescription for BENADRYL 50mg three times daily for 5 days. At the time of the report on 08-APR-2010 she was recovering. There were no laboratories diagnostics studies performed. Fever, itching and generalized rash on the abdomen, arms and neck were considered to be an other important medical event by the primary reporter. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Papanicolaou smear abnormal; Papilloma viral infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385236-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		15-Apr-2010	16-Apr-2010	IN	WAES1004USA01238	16-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Epilepsy

Symptom Text: Information has been received from a physician concerning a 16 year old female patient with epilepsy who on unspecified dates was vaccinated with two doses of GARDASIL, 0.5 ml, IM. Concomitant therapy included hormonal contraceptives (unspecified), started "about the same time as the first dose of GARDASIL". The dosage of the birth control pill was increased due to the patient also taking LAMICTAL. The physician reported that the patient had experienced an increase in frequency of seizures since her first dose of GARDASIL. The physician reported that the patient was under the care of an unspecified neurologist due to her known history of epilepsy. At the time of the report the patient's outcome was not specified. The patient sought medical attention by an office visit. No diagnostic tests were performed. Upon internal review increase in frequency of seizures was determined to be an other important medical event. Additional information has been requested.

Other Meds: Hormonal contraceptives; LAMICTAL

Lab Data: None

History:

Prex Illness: Epilepsy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: 385237-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Feb-2010	20-Feb-2010	17	15-Apr-2010	16-Apr-2010	FR	WAES1004USA01446	16-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ29430		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Cough, Henoch-Schonlein purpura, Myalgia, Petechiae, Pyrexia, Urticaria

Symptom Text: Case reported by Health Authority (case n. 114647) through SPMSD (local case n. IT164/10). An 11 year old female was vaccinated IM on 03-FEB-2010 with one dose of GARDASIL (batch n. NK19200, lot# NJ29430). The patient was allergic to house dust mite. On 20-FEB-2010 she presented with moderate fever (38C) and cough (not considered as an adverse event) concomitantly treated with CLENIL for one day on 21-FEB-2010 and PARACODINA for two days on 22-FEB-2010 and 23-FEB-2010. On 26-FEB-2010 onset of petechiae to the lower limbs, the medical guard diagnosed urticaria (not confirmed by the pediatrician). On 01-MAR-2010 the patient was evaluated by her pediatrician who diagnosed Henoch-Schonlein vasculitis. On 06-MAR-2010 she was admitted to the hospital due to onset of muscle and abdominal pain. She was discharged on 07-MAR-2010 with the recommendation of performing frequent urine analysis for proteinuria/hematuria. The diagnosis of Henoch-Schonlein vasculitis was confirmed by the hospital. At the time of reporting the patient had not yet recovered. The final outcome was not reported. HA coded "vasculitis Henoch Schonlein Like". The case is closed. Other business partner numbers included: E2010-02225.

Other Meds: CLENIL, 21Feb10 - 21Feb10; PARACODINE, 22Feb10 - 23Feb10

Lab Data: Allergy test, house dust mite; body temp, 20Feb10, 38 C

History:

Prex Illness: House dust mite allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385290-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Apr-2010	16-Apr-2010	0	16-Apr-2010	16-Apr-2010	WA		16-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3021AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52BO37AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vertigo

Symptom Text: Episode of vertigo when stand up 3 minutes after vaccine given. Given crackers and juice, and supine for 20 minutes. Vertigo returned within 5 minutes of standing. Supine on left side and given 12 oz water over the next 30 minutes. Episode of vertigo returned with standing. After a second period of 30 minutes supine on left side and 3 more oz of water, patient was able to stand without vertigo returning for the next hour

Other Meds:

Lab Data: Bloodpressure 100/66 supine Pulse 76

History: No

Prex Illness: No, but had not eaten breakfast

Prex Vax Illns:

Vaers Id: 385301-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Jul-2009	17-Jul-2009	0	16-Apr-2010	19-Apr-2010	FR	WAES0907USA05098	19-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Hiccups, Nausea

Symptom Text: Information has been received via agency as part of a business agreement, from a physician concerning a 13 year old female patient who on 17-JUL-2009 at 12:30 pm was vaccinated with the first dose of GARDASIL intramuscularly into her left deltoid. This report was part of a post-marketing surveillance program. It was reported that on 17-JUL-2009 at 04:00 pm, she presented to the Health Center with abdominal pain, nausea and hiccups. She was admitted to Health Center and provided dicyclomine and ZOFER injections and kept in the Health Center for observation. On 17-JUL-2009, at 05:45 pm, she was referred to the Hospital for further observation as the Health Center did not have the facility to provide such services after 06:00 pm. She was admitted to the hospital, Casualty on 17-JUL-2009 at 06:50 pm. On admission, she was conscious, coherent. Her body temperature was normal, pulse was 80/mts, blood pressure was 120/80 mm/Hg. On examination her abdomen was soft, no obvious mass or tenderness. Blood test for Hb, ESR, ultrasound of the abdomen and CT scan of the head was done. All tests were reported as normal. She had no further complains and her parent took her home early morning of 18-JUL-2009, prior her being seen by medical staff and getting discharged and was found to be normal after follow up. On 19-JUL-2009, project investigator visited her, and she was well and had no complains. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure measurement, 120/80 mm/Hg; diagnostic laboratory test, Hb test; normal; computed axial tomography, of the head; normal; ultrasound, abdomen;normal; body temp, normal; total heartbeat count, 80 /mts; erythrocyte sedimentation

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385302-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-Jan-2010	21-Feb-2010	25	16-Apr-2010	19-Apr-2010	FR	WAES1004USA00711	19-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ39100	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Neuropathy peripheral, Pain in extremity

Symptom Text: Information was obtained on request by the company from the agency via a Case Line Listing through CSL as part of a business agreement, concerning a 17 year old female patient who on 27-JAN-2010 was vaccinated with the first dose of GARDASIL 0.5 ml, intramuscularly (lot #NJ39100, batch #NK55510). Concomitant therapy included MICROGYNON. On 21-FEB-2010 the patient experienced leg pain severe and neuropathy severe. The patient's leg pain (severe) and neuropathy (severe) had definite improvement but had not yet recovered. The agency considered that leg pain severe and neuropathy severe were unlikely related to therapy with GARDASIL. The original reporting source was not provided. Additional Information is not expected.

Other Meds: MICROGYNON

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385303-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	01-Mar-2010		16-Apr-2010	19-Apr-2010	--	WAES1004USA01848	19-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a Nurse at the physician's office who heard from another Nurse that a patient came in to the office to receive the third dose of GARDASIL and the friend of the patient told her not to get the third dose because she knew of another girl that received the third dose of GARDASIL and died "within the last month" (cause of death not reported). It was unknown if the patient sought medical attention. Attempts are being made to verify the existence of an identifiable patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **385323-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Apr-2010	14-Apr-2010	5	16-Apr-2010	19-Apr-2010	MI		19-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3096AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365CA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral, Rash

Symptom Text: Four raised plaques about 1.5 cm across each, in square pattern on left upper arm - two with puncta in middle. Spots developed on 4/14/10, five days after vaccines. Diagnosed skin rash, possible bug bite. BENADRYL 25 mg every 6 hrs PRN.

Other Meds: None

Lab Data: None

History:

Prex Illness:

Prex Vax Illns: Erythema and duration. No rasied lesions~Tdap (no brand name)~1~12.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Apr-2010	15-Apr-2010	1	16-Apr-2010	19-Apr-2010	MI		19-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	10767	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1318Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash erythematous

Symptom Text: Red rash, itching.-motrin, ice, benadryl.

Other Meds:

Lab Data:

History: sulfa

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385344-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Apr-2010	15-Apr-2010	1	16-Apr-2010	19-Apr-2010	MI		19-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF460CA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1076Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1318Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site warmth

Symptom Text: erythems, itching, and warmth over injection site. Approximately size of a quarter. Treated with motrin, ice, and benadryl.

Other Meds:

Lab Data: There was currently a pertussis outbreak at this childs school.

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **385345-1** **Related reports:** 385345-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	12-Oct-2007	05-Jan-2008	85	16-Apr-2010	19-Apr-2010	OH		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	3	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Angioedema, Auricular swelling, Autoimmune disorder, Bronchitis, Chills, Cough, Drug hypersensitivity, Erythema, Feeling hot, Hypersensitivity, Idiopathic urticaria, Nasal congestion, Oropharyngeal pain, Pruritus, Rash, Rash macular, Skin burning sensation, Urticaria, Wheezing

Symptom Text: Ear lobes very swollen, red and itchy. Since then, I have full body hives. The following information was obtained through follow-up and/or provided by the government. records received 04/26/2010. Dermatology clinic records for DOS 04/16/10. Assessment: Urticaria Idiopathic. Patient presented for initial visit with c/o intermittent chronic hives x 2 yrs. Initially, hives originated on ear lobes. Ear lobes itch, swell, are hot to touch and burn. Hives flare about once a week. Examination noted urticaria on neck, face, ears. Plan: follow-up in 2 wks records received 04/26/2010. Clinic records 03/17/2008 -03/05/2009. Visit 3/17/2008: Patient c/o hives x 2days after starting Z-Pak and also had cough with congestion. Examination noted patient had slight wheeze upper lobes and rash/hives on R. elbow, stomach and back. Assessment: Bronchitis and Allergic reaction to Z-Pak. Plan: Levaquin, Prednisone, And Albuterol. Visit 6/06/2008: Patient presented with c/o hives all over since yesterday. Assessment: Urticaria. Plan: Kenalog, Zantac. Visit 3/05/2009: Patient presented with c/o hives x 1 yr. Patient noted to have hives- head to toe. Assessment: Urticaria. Plan: Levaquin. records received 04/27/10 & 04/29/10. Immunization Gardasil rec. for 2007 and clinic rec for DOS 2/15/2008-3/30/10. Visit rec 2/15/08 for follow-up of perennial allergic rhinitis. Patient has completed 5 yrs. of immunotherapy and on maintenance phase. Assessment stable on maintenance phase of immunotherapy. Follow-up visit: Patient with contact urticaria from new body lotion and shampoo. Visit 09/22/08, patient presented with hives. Patient reported having hives on a daily basis. Examination noted giant urticaria scattered throughout body. Impression: Perennial allergic rhinitis and chronic idiopathic urticaria. Plan: Hold immunotherapy. Start Xyzal, Zantac, VoSpire and Prednisone taper. On follow-up, pt. improved and received a flu shot. Visit 01/05/09, Examination noted few scattered urticarial lesions on shoulders and upper back. No angioedem

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 04/27/10 LABS and DIAGNOSTICS: Pulmonary function test-abnormal (mild obstructive disease).

History: Seasonal allergies- grasses, trees, dust mites. Allergy to ceclor, biaxin, steri strips The following information was obtained through follow-up and/or provided by the government. 04/26/10 PMH: Allergy to Ceclor, Biaxin, Steri-Strips and Azithromycin, back pain/bulging disc, Cushing's.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **385345-2 (S)** **Related reports:** 385345-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-Oct-2007	05-Jan-2008	76	22-Apr-2010	23-Apr-2010	OH		23-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Auricular swelling, Erythema, Pruritus, Urticaria

Symptom Text: I received the final injection of the GARDASIL vaccine on 10/21/2007 and on 01/05/2008 I woke up in the morning with red, swollen and itchy ear lobes. Since then, I have had full body hives.

Other Meds:

Lab Data:

History: Allergies to grasses, trees, dust mites. Allergy to CECLOR, BIAXIN, steri strips.

Prex Illness:

Prex Vax Illns:

Vaers Id: **385346-1 (S)** **Related reports:** 385346-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Mar-2010	13-Apr-2010	27	16-Apr-2010	19-Apr-2010	MD		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Diabetes mellitus, Fatigue, Headache, Hyperglycaemia, Malaise, Mucosal dryness, Nausea, Nocturia, Polydipsia, Polyuria, Thirst

Symptom Text: new onset diabetes mellitus hyperglycemia, serum glucose 506 hospitalized for 24 hrs IV fluids, insulin and education The following information was obtained through follow-up and/or provided by the government. Hospital records and transfer/discharge summary received 4/20/10. Service dates 4/12/10 to 4/14/10. Diagnosis: Diabetes Mellitus. Patient presents with 1-2 week hx fatigue, polyuria, polydipsia, intermittent headache, abdominal pain and nausea. 8 lb weight loss. Insulin tx initiated. Discharged to home. PCP medical records received 4/19/10. Service dates 3/17/10 to 4/12/10. Assessment: Diabetes Patient more tired, very thirsty, drinking lost of water, getting up at night to void multiple times. Doesn't feel well. Dry tacky (oral) mucous membranes.

Other Meds:

Lab Data: serum glucose 506. The following information was obtained through follow-up and/or provided by the government. LABS and DIAGNOSTICS: Whole Blood Glucose: 330 mg/dL (H). Urine Ketones (+). LABS and DIAGNOSTICS Urinalysis - Glucose 2000+, ke

History: none. The following information was obtained through follow-up and/or provided by the government. PMH: Warts tx by dermatologist. Fracture foot. Varicella post vaccine.

Prex Illness: no

Prex Vax Illns:

Vaers Id: **385346-2 (S)** **Related reports:** 385346-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Mar-2010	13-Apr-2010	27	15-Jun-2010	16-Jun-2010	--	WAES1005USA04132	16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Diabetes mellitus, Fatigue, Headache, Hyperglycaemia, Malaise, Mucosal dryness, Nausea, Pollakiuria, Polydipsia, Polyuria, Thirst, Weight decreased

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 14 year old female patient with a history of warts treated by dermatologist, fracture foot and varicella post vaccine who on 17-MAR-2010, was vaccinated with the third dose of GARDASIL IM into her left arm (lot # 662300/0100Y). There was no pre existing illness. On 13-APR-2010, the patient experienced new onset diabetes mellitus and hyperglycemia. Serum glucose was 506. The patient was hospitalized for 24 hours and treated with IV fluids, insulin and education. On 20-APR-2010, hospital records and transfer/discharge summary was received. Service dates was 12-APR-2010 to 14-APR-2010. The diagnosis was diabetes mellitus. The patient presented with 1-2 week history of fatigue, polyuria, polydipsia, intermittent headache, abdominal pain and nausea, 8 lb weight loss. Insulin treatment was initiated. The patient was discharged home. Primary care physician medical records were received on 19-APR-2010. Service dates was 17-MAR-2010 to 12-APR-2010. Assessment was diabetes. The patient felt more tired, very thirsty, drinking lots of water and getting up at night to void multiple times. The patient did not feel well, and had dry tacky (oral) mucous membranes. The following lab tests were performed: serum glucose was 506 which was high, whole blood glucose was 330 which was high, urine ketones was positive, urinalysis showed glucose of 2000+, ketones large, sodium was 132 which was low, chloride was 93 which was low. The patient required an emergency room visit. No further information is available. Diabetes mellitus, hyperglycemia, fatigue, polyuria, polydipsia, intermittent headache, abdominal pain, nausea, very thirsty, does not feel well, dry tacky mucous membranes and drinking lots of water and getting up at night to void multiple times were considered to be immediately life-threatening. The original reporting source was not provided. The VAERS ID# is 385346. A preliminary lot check inves

Other Meds: Unknown

Lab Data: serum glucose, 506 mg/d; blood glucose, 330 mg/d; total urine ketones, +; urine glucose (quant), 2000+; serum sodium, 132 mmol; urinalysis, ketones large; serum chloride, 93 mmol

History: Wart; Foot fracture; Varicella

Prex Illness:

Prex Vax Illns:

Vaers Id: **385377-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	08-Apr-2010	09-Apr-2010	1	19-Apr-2010	20-Apr-2010	OH		04-May-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1000Y	1	Right arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U3019AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0100Y	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3250AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pruritus, Injection site swelling, Injection site urticaria, Injection site vesicles

Symptom Text: April 9, 2010 4:10 PM. Mother & client came to county Health Department concerned about redness & swelling & itching at VARIVAX injection site. Noted redness, induration "hive - like" appearance with lighter edge measuring 2" wide & 1 1/2" depth. R.N., C.N.P. advised ice pack 20 min. on & 20 min. off, if worse or blisters to go to Urgent Care. April 10, 2010 to Urgent Care due to blisters within the welt. Triple antibiotic & gauze wrap ordered. April 15, 2010 per mother blisters gone, swelling decreased, but some redness remains.

Other Meds: None

Lab Data:

History: Medication: OMNICEF (hives); aceomadative esotropia

Prex Illness: None Known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385398-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Apr-2010	01-Apr-2010	0	19-Apr-2010	20-Apr-2010	AR	AR1013	30-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3353AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1151Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3016AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Fall

Symptom Text: After receiving 4 vaccines, patient stood up & sit on exam table waiting for sister to get vaccinated. Pt fell to the floor after sl. waving of arms & legs x approx 3 secs. Nurse called for help v/s assessed, pt alert & reports didn't remember falling to floor. Redness to left shoulder.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385457-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	01-Jan-2010		20-Apr-2010	20-Apr-2010	--		20-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Patient developed possible lvll computed seizures in Jan 2010 after completing the third GARDASIL in Dec 2009. MRI revealed single area of abnormal signal in right hemisphere white matter. Kug left temporal seizure activity. Unknown if vaccine causative or related. Vaccine administered by pediatrician.

Other Meds:

Lab Data: Onset of partial epilepsy beginning in Jan 2010. MRI Brain single area of leuko-encephalopathy.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **385473-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	09-Jan-2009	09-Jan-2009	0	20-Apr-2010	21-Apr-2010	--	WAES0901USA01624	21-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a medical assistant for GARDASIL, a pregnancy registry product; concerning a 24 year old female with no known medical history or drug allergies, who on 09-JAN-2009 was vaccinated with a 0.5 mL first dose of GARDASIL (lot # 661046/0546X), intramuscularly. Concomitant therapy included NUVARING. On 12-JAN-2009 the patient discovered that she was pregnant. On 09-JAN-2009 the patient had an RPR, HIV and herpes 1 and 2 tests. The patient performed a home urine pregnancy that was positive, and the office performed another urine pregnancy test on 12-JAN-2009 that was positive. No adverse effects reported. The patient sought medical attention through an office visit. The reporter stated that the patient was planning to terminate the pregnancy (not due to the vaccine). Follow up information received from a home care coordinator indicated that the patient wasn't pregnant during the GARDASIL vaccination series; (the patient finished the GARDASIL series on an unspecified date). Follow up information received from the home care coordinator indicated that the patient had a termination of her pregnancy on 27-MAR-2009. The patient returned to the office for her follow up evaluation and was considered recovered without complications. Additionally she was provided contraceptions. She also mentioned that the patient returned for the second and third GARDASIL doses (dates and lot numbers not provided). Upon internal review termination of her pregnancy was determined to be an other important medical event. No further information is available.

Other Meds: NUVARING

Lab Data: urine beta-human, 01/12/09, positive; urine beta-human, positive; Rapid plasma reagin, 01/09/09; whole blood HIV-1, 01/09/09; herpes simplex virus, 01/09/09

History:

Prex Illness: Pregnancy NOS (LMP = 1/2/2009)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385476-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	22-Jan-2009	22-Jan-2009	0	20-Apr-2010	21-Apr-2010	RI	WAES0904USA01160B1	21-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Congenital anomaly, Drug exposure during pregnancy, Patent ductus arteriosus, Urine human chorionic gonadotropin positive, Ventricular septal defect

Symptom Text: Information has been received from a physician for GARDASIL, a Pregnancy Registry product, concerning a baby. The baby's 19 year old mother with no pertinent medical history or drug reactions/ allergies who on 22-JAN-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL (lot number reported as "0615X"). There was no concomitant medication. On 12-FEB-2009, the mother had her intrauterine device removed. Then the mother discovered that she was pregnant. On 03-MAR-2009, urine pregnancy test was performed at the office with positive result. The mother's last menstrual period was 18-JAN-2009, the estimated delivery date was 25-OCT-2009. On 26-MAR-2009, the mother was vaccinated IM with the second 0.5 ml dose of GARDASIL (661952/1129X). No adverse effect reported. The mother sought medical attention by phone visit. Follow-up information was received from the physician concerning the 19 year old mother with once previous pregnancy and full term delivery and no birth defect in previous pregnancy. Other medication in the pregnancy included prenatal vitamins. Follow-up information has been received from the physician concerning the 19 year mother who on an unspecified date was delivered the "normal infant" baby. The physician also stated that the infant experienced congenital anomaly of small ventricular septum defect and patent ductus arteriosus. The mother's experience has been captured in WAES 0904USA01160. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385479-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
-0.7	M	05-Jun-2009	05-Jun-2009	0	20-Apr-2010	21-Apr-2010	--	WAES0906USA01565B1	05-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ankyloglossia congenital, Drug exposure during pregnancy, Oxygen consumption decreased, Umbilical cord abnormality

Symptom Text: Information has been received from a consumer concerning her newborn son who on 05-JUN-2009 was exposed to a dose of GARDASIL in utero. The patient was also exposed to prenatal vitamins (unspecified). On 11-FEB-2010 the patient developed tongue tie. It was also reported that during labor the baby grabbed the umbilical cord during contractions, resulting in low oxygen intake. The patient's outcome was unknown. The mother's experience has been captured in WAES # 0906USA01565. Additional information has been requested.

Other Meds: Vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Breast lump

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385480-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	02-Jun-2009	02-Jun-2009	0	20-Apr-2010	21-Apr-2010	--	WAES0907USA00225B1	22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Heart rate irregular, Neonatal disorder

Symptom Text: Information has been received concerning a female who on 02-JUN-2009 was vaccinated with the first dose of GARDASIL (lot # 658271/0558X) while pregnant (WAES 0907USA00225). Subsequently she delivered a health normal baby. On an unspecified date the baby experienced irregular heart rate and was hospitalized for 3 weeks. At the time of the report the patient status was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 385485-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	03-Mar-2008	01-Jun-2008	90	20-Apr-2010	21-Apr-2010	FR	WAES1004USA02053	19-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthritis, Musculoskeletal pain, Musculoskeletal stiffness, Polyarthritis

Symptom Text: Information has been received from a general practitioner concerning a 19 year old female patient with a history of eczema who on 03-MAR-2008 was vaccinated with the third dose of GARDASIL (Batch number not reported). In June 2008, the patient developed inflammatory rheumatism or polyarthritis. She had received the second dose of GARDASIL on 06-MAY-2008. The patient was hospitalized for further investigations and received corrective treatment with methotrexate. At the time of reporting she was stabilized. Additional information was received. The patient's initials and date of birth were provided. She had a history of eczema on the hands. She developed the first symptoms in June 2008. Consequently the suspect dose of GARDASIL was the second one, administered on 06-MAY-2008. She had received the first dose of GARDASIL on 03-MAR-2008. In June 2008, she was seen in rheumatological consultation and X-ray of the hand was performed. It showed an inflammatory syndrome of one finger of the right hand. The patient also presented morning stiffness. She was hospitalized 2 days in February 2009 for complete work-up. She had sedimentation rate of 7 (units not reported), CRP of 11 (units not reported); however, the patient was already on treatment at that time. X-ray found arthritis of the fifth interphalangeal joint. The rheumatologist's conclusion was asymmetrical polyarthritis, is one side more impaired than the other, affecting distal interphalangeal joints with radiological signs of inflammatory arthritis and probably corresponding to psoriatic rheumatism. The reporting physician believed that it was not psoriatic rheumatism because the patient had a history of eczema on the hands rather than a history of psoriasis. Case linked with non-serious report E2010-02323 (same reporter, same product, similar AE). Other business partner numbers include: E2010-02322. No further information is available.

Other Meds: Unknown

Lab Data: X-ray, ??Jun08, Inflammatory syndrome of one finger of the right hand; X-ray, ??Feb09, Arthritis of the fifth interphalangeal joint; serum C-reactive protein, ??Feb09, 11; erythrocyte sedimentation rate, ??Feb09, 7

History: Eczema

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385486-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Mar-2010	18-Mar-2010	0	20-Apr-2010	21-Apr-2010	FR	WAES1004USA01994	22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ37700	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Muscle contractions involuntary, Oedema peripheral, Pain in extremity, Paraesthesia, Polyneuropathy, Vaccination site reaction

Symptom Text: Information has been received from a Health Authority (case n. 114942, local case n. IT176/10) concerning a 11 year old female who on 18-MAR-2010 was vaccinated with the first dose of GARDASIL (batch number NK31720, lot number NJ37700) IM in the right deltoid. On the same day she presented with pain in the right arm and swelling. She was treated with TACHIPIRINA with little benefit. On 19-MAR-2010 onset of paresthesia right arm and pain left arm. She was taken to the Emergency Room (ER) where she was treated with ice packs and TACHIPIRINA. On 20-MAR-2010 neurological consultation and electromyography that was negative. On 23-MAR-2010 she was admitted to the hospital for contraction to the shoulder and right hand. A rachicentesis performed showed radiculoneuritis. The outcome was recovered on 27-MAR-2010. HA coded muscle contraction, paresthesia, polyradiculoneuritis and vaccination site reaction. The case is closed. Other business partner numbers include E2010-02307.

Other Meds: Unknown

Lab Data: electromyography, 10Mar10, negative; spinal tap, 23?Mar10, rachicentesis showed radiculoneuritis

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **385488-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Oct-2007	Unknown		20-Apr-2010	21-Apr-2010	FR	WAES1004USA01993	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1536F	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Cutaneous vasculitis, Emotional distress, General physical condition abnormal, Infection, Leukocytoclastic vasculitis, Vaccine positive rechallenge

Symptom Text: Information has been received from a Health Authority (reference number PEI20100008572) concerning an 18 year old female patient with a history of allergic rhinitis who on 17-OCT-2007 was vaccinated with the first dose of GARDASIL (batch number NG01520, lot number 1536F). Concomitant therapy included cetirizine every spring time due to allergic rhinitis. Two reporting forms with ambiguous information were sent. According to one the onset was in October 2007, according to the other the onset was on 12-NOV-2007. No symptoms were reported. According to a histologic finding, the patient had a "cutaneous vasculitis of small blood vessels with leucocytoclastic vasculitis of the lower extremities" beginning at the legs, in May 2009 additionally arms and trunk were concerned. The patient was treated initially with corticosteroids and mycophenolate (April 2009). Under treatment with azathioprine from May to October 2009 the symptoms stopped but reappeared at both lower legs after stop of treatment. At the time of reporting the patient had not recovered. One the reporters stated a "persisting damage". The patient was vaccinated with the second (batch number NG00020, lot number 0277U) and third dose (batch number NG00020, lot number 0277U) of GARDASIL on 07-DEC-2007 and in September 2008 (1st or 9th, difference between both reporting forms), respectively with positive rechallenge of vasculitis. Additional symptoms appeared after "physical and mental stress" and in the scope of infections. HA coding: leucocytoclastic vasculitis and vasculitis. Additional information has been requested. Other business partner numbers include E2010-02330.

Other Meds: cetirizine hydrochloride

Lab Data: Unknown

History: Rhinitis allergic

Prex Illness: Rhinitis allergic

Prex Vax Illns:

Vaers Id: 385489-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Dec-2008	10-Aug-2009	235	20-Apr-2010	21-Apr-2010	FR	WAES1004USA01448	22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Aplastic anaemia, Bone marrow transplant, No reaction on previous exposure to drug

Symptom Text: Information has been received from a health authority (HA ref. DK-DKMA-20100331) on 08-APR-2010. It was reported that a 15 year old female patient (weight 50 kg, height 160 cm) who on 29-JUN-2009 was intramuscularly vaccinated with the third dose of GARDASIL (site of administration not reported). On 10-AUG-2009, the patient was diagnosed severe aplastic anaemia. As a consequence, the patient underwent bone marrow transplantation on 07-SEP-2009. It was reported that the bone marrow transplantation was successful and that the patient recovered (not further specified). Date and duration of hospitalization was not reported. It was reported that it was unlikely that the vaccination could have caused the aplastic anaemia. The patient was vaccinated with the first and second dose of GARDASIL (batch number, route and site of administration not reported) on 18-DEC-2008 and 19-FEB-2009, respectively. No adverse reaction was reported. Severe aplastic anaemia and bone marrow transplant were considered to be immediately life-threatening by the Health Authority. Case is closed. Other business partner number include E2010-02277. No further information is available.

Other Meds: Unknown

Lab Data: unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **385490-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Aug-2009	01-Dec-2009	100	20-Apr-2010	21-Apr-2010	FR	WAES1004USA01447	22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ligament disorder, No reaction on previous exposure to drug, Rheumatoid factor increased, Streptococcus test positive, Swelling, Tendon disorder

Symptom Text: Information has been received from a gynecologist concerning a 16 year old female patient who on 23-AUG-2009, was vaccinated with her first dose of GARDASIL (Lot # 1427U, batch# NH17960) which was well tolerated and on 27-OCT-2009, was vaccinated IM with her second dose of GARDASIL (Lot # 1316U, batch# NH38490) into her deltoid muscle. Since December 2009, the patient had swollen tendon sheath and "thick" ligaments (Achilles tendon, arms and wrists) (verbatim by reporter). The rheumatoid factor and ASL were increased (no values reported). At the time of the reporting the symptoms were ongoing. The reporting physician considered swollen tendon sheath and "thick" ligaments (Achilles tendon, arms and wrists) to be other important medical events. Other business partner numbers included E2010-02245. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: 385492-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Feb-2009	Unknown		20-Apr-2010	21-Apr-2010	FR	WAES0904USA03664	22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1201U	0	Left arm	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Decreased appetite, Dyskinesia, Eyelid disorder, Fall, General physical health deterioration, Headache, Mastication disorder, Muscle contractions involuntary, Muscular weakness, Nausea, Palatal disorder, Speech disorder, Weight decreased

Symptom Text: Information has been received from a healthcare professional on 06-APR-2009. It was reported by a gynaecologist that a 14 year old female patient was vaccinated with a first dose of GARDASIL (lot # 1201U, batch # NG29050) SC into the left upper arm on 06-FEB-2009. A few days P.V. the patient developed asthenia and weakness of the knee joints ("knees like pudding"), so she "slumped down". The final outcome was unknown to the reporter. Follow up information received on 12-APR-2010. Based on additional information from Health Authority (reference number PEI2010003705), this previously non-serious case was updated to serious with hospitalization as serious criteria. Approximately one to two weeks post the vaccination the patient's general condition increasingly reduced. The patient lost of appetite with a loss of weight (15kg) and experienced chewing difficulty and hindered closing of her mouth. Additionally her knee "buckled". Because of muscle weakness of the legs she could not attend sports at school anymore. Since November 2009 the patient showed speech disorder (indistinct/"washy" speech). Since January 2010 the patient could not completely close her eyelids, soft palates were "hanging" and she experienced fasciculation of tongue, headache and nausea. On 13-JAN-2010 the patient was hospitalized and treated with logopedics and physiotherapy. Investigations like MRI and lumbar puncture were normal. Up to the time of reporting to HA (20-JAN-2010) no diagnosis was established nor drug treatment was started. The outcome was "unknown". HA code: appetite lost, fasciculation, headache, loss of weight, muscle weakness, speech disorder, reduced general condition and chewing difficulty. Other business partner numbers included: E200903046. No further information is available. File closed.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 13?Jan10, normal; spinal tap, 13?Jan10, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **385500-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	16-Jun-2009	21-Jun-2009	5	20-Apr-2010	21-Apr-2010	FR	WAES1004USA01444	21-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Myasthenia gravis

Symptom Text: Information has been received from a health authority (HA reference No. PEI2009032065). A 26 year old female patient with history of myasthenia gravis with diplopia in 2006 and CIN II (cervical intraepithelial neoplasia grade II) was vaccinated with the first dose of GARDASIL on 16-JUN-2009 (Lot #, injection route and site not reported). Concomitant therapy included hormonal contraceptives (unspecified), levothyroxine Na and NEXIUM MUPS. On 21-Jun-2009, the patient developed a relapse of myasthenia gravis (second occurrence of myasthenia). The patient was treated with 50 mg prednisolone daily from 21-JUN-2009 to 17-AUG-2009, then 30 mg daily. A blood sample was taken on 07-JUL-2009. Autoimmune antibodies (against acetylcholine receptor or MUSK: muscle specific kinase, not specified) showed a value of 16.91 nmol (normal: < 0.20 nmol). A thoracic MRI (date not reported) had shown no enlargement of thymus and therefore no thyrectomy was performed. A second dose of GARDASIL was administered on an unspecified date and was well tolerated. Duration and outcome were not reported. The reporting agency considered myasthenia gravis aggravated to be other important medical event. Other business partner numbers include E2010-02239. The file is closed. No further information is available.

Other Meds: NEXIUM MUPS; hormonal contraceptives (unspecified); levothyroxine Na

Lab Data: magnetic resonance imaging, thoracic: No enlargement of thymus; acetylcholine receptor antibody test, 07Jul09, 16.91 nmol

History:

Prex Illness: Myasthenia gravis; Cervical intraepithelial neoplasia II; Contraception

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385501-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Nov-2009	09-Nov-2009	0	20-Apr-2010	21-Apr-2010	FR	WAES1004USA01445	22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Condition aggravated, Dizziness, Headache, Loss of consciousness, Musculoskeletal stiffness, Syncope

Symptom Text: Information has been received from a health authority (HA reference No. ES-AGEMED-914617346). A 15 year old female patient was vaccinated IM with a dose of GARDASIL on 09-NOV-2009 (batch # and site of administration not reported). After receiving the vaccination with GARDASIL the patient experienced loss of consciousness, which was preceded by light-headedness and stiff limbs. The patient was taken to the emergency room due to residual headache and amnesia of the syncope episode. It was reported that the patient had had a prior syncopal episode after having a blood sample taken. To be noted, the health authorities coded only syncope, felt faint and rigidity of limbs. According to the report the patient recovered from syncope, rigidity of limbs and felt faint on the same day, 09-NOV-2009. No further information was reported. Case reported as serious by the health authority with other medically important condition as criteria. The case is closed. Other business partner numbers include E2010-02240. The file is closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385502-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	13-Oct-2009	13-Oct-2009	0	20-Apr-2010	21-Apr-2010	--	WAES1004USA01925	22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Haemorrhage, Loss of consciousness

Symptom Text: Information has been received from a 24 year old female consumer with no known drug reactions or allergies and nausea who on 13-OCT-2009 was vaccinated with the first dose of GARDASIL. Concomitant therapy included MACROBID and OTC nausea medicine. The consumer reported that on 20-OCT-2010, in the clinic were she works, she took a pregnancy test and she found that she was pregnant. It was reported that the consumer LMP was "3 weeks to a month" before, on approximately 13-SEP-2009 and the estimated date of delivery (EDD) is 20-JUN-2010. The consumer reported that on an unspecified date she had an ultrasound performed and it was found that the baby will need to have "open heart surgery when she is born" because the baby's "Tetralogy Fallot" condition. The consumer also reported that on unspecified dates, she had been in and out of the hospital (hospital unknown) due to her bleeding and that she had been passing out. It was noted that the patient had been seeing a number of specialist that performed several tests (results not provided) in regards to the baby's condition. At the time of the report, the patient's outcome was unknown. Fallot tetralogy was considered a congenital anomaly. The baby's experience has been captured in WAES 1004USA01925B1. Additional information has been requested.

Other Meds: MACROBID

Lab Data: Ultrasound, The baby will need to have "open heart surgery when she born", the baby had "Tetralogy Fallot"; Beta-human chorionic, 10/20/09, Positive

History:

Prex Illness: Pregnancy NOS (LMP = 9/13/2009); Nausea

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385503-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	13-Oct-2009	13-Oct-2009	0	20-Apr-2010	21-Apr-2010	--	WAES1004USA01925B1	22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Congenital anomaly, Drug exposure during pregnancy, Fallots tetralogy

Symptom Text: Information has been received from a consumer concerning her baby who on 13-OCT-2009 was exposed via her mother with the first dose of GARDASIL. Concomitant therapy included MACROBID and OTC nausea medicine. The consumer reported that on an unspecified date she had an ultrasound performed and it was found that her baby will need to have "open heart surgery when she is born" because the baby's "Tetralogy Fallot" condition. It was noted that the consumer had been seeing a number of specialist that performed several tests (results not provided) in regards to the baby's condition. At the time of the report, the baby's outcome was unknown. Tetralogy Fallot was considered a congenital anomaly. The mother's experience has been captured in WAES 1004USA01925. Additional information has been requested.

Other Meds: MACROBID

Lab Data: ultrasound, Tetralogy Fallot

History:

Prex Illness: Nausea

Prex Vax Illns:

Vaers Id: **385504-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	23-Apr-2009	23-Nov-2009	214	20-Apr-2010	21-Apr-2010	FR	WAES1004USA01995	22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local reaction, Pain

Symptom Text: Information has been received from a Health Authority (reference number 20600549) concerning a 22 year old female patient with a history of drug intolerance to ibuprofen, who on 23-APR-2009 was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL (batch number and site not reported). The patient was also receiving BINOVUM and chloramphenicol ophthalmically for unreported indications. On 23-NOV-2009, seven months post vaccination, the patient experienced an ache in the face, neck, shoulder and chest and severe local reaction. The patient has not yet recovered. Both the reporter and the health authority considered this to be a serious reaction due to other medically significant reason. The health authority coded the events of ache and local reaction. Other business partner numbers include E2010-02344. No further information is available.

Other Meds: BINOVUM; chloramphenicol

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **385505-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	09-Jul-2009		20-Apr-2010	21-Apr-2010	--	WAES1004USA02176	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Blood human chorionic gonadotropin decreased, Drug exposure during pregnancy, Progesterone abnormal

Symptom Text: Information has been received from a registered nurse for GARDASIL, a Pregnancy Registry product, concerning a 27 year old female patient with no pertinent medical history and no drug reactions/allergies who in 2007, at the age of 25 year was vaccinated with a series of GARDASIL without incident. There was no concomitant medication. On approximately 09-JUL-2009, the patient became pregnant. Her LMP was approximately on 25-JUN-2009. Expected due date was April 2010. In August or September 2009, the patient miscarried at two months pregnant. Upon internal review, miscarriage was determined to be an other important medical event. The patient subsequently became pregnant again and experienced blood beta-human chorionic gonadotropin level decreased and progesterone level abnormal (WAES#1004USA02387). Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 6/25/2009)

Prex Vax Illns:

Vaers Id: **385512-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	31-Mar-2010	31-Mar-2010	0	20-Apr-2010	21-Apr-2010	CA		22-Apr-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB311BA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0819X		Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3064AA		Right arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52BO43BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Hyperventilation, Muscle contracture, Nausea, Pallor

Symptom Text: Patient became pale, nauseated and dizzy. Patient hyperventilating. Unable to control breathing. Bilateral hand and shoulder contractures noted. Patient placed in Trendelenburg. Color returned to normal and dizzness and nausea resolved. Contractures on left hand and shoulder resolved. Patient given juice and encouraged to breathe normally. Right hand remained contracted. Patient states she is "double jointed" and sometimes wakes in the morning with hand contractures. Patient ambulatory.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385563-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	06-Apr-2010	07-Apr-2010	1	21-Apr-2010	22-Apr-2010	NJ		23-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2908AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0739Y	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0978Y	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Injection site pain, Myalgia, Pyrexia, Syncope

Symptom Text: 4-6-10 - Pt c/o feeling dizzy after imm. Pt went bike riding after lunch for most a day. During evening (R) leg muscle was achy - 6 days in duration. Pt also c/o headache 4/7 and 4/8 pt treated with TYLENOL. Pt states that she "collapsed" 4/7 but was able to stand up - (L) arm sore at site of injection - 4/12/10 febrile 24 hrs.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385591-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Apr-2008	08-May-2008	16	21-Apr-2010	22-Apr-2010	AL	WAES1004USA02175	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Epilepsy

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on 22-APR-2008 was vaccinated with the first dose of GARDASIL (lot# not reported). On 08-MAY-2008 the patient developed a seizure. The patient then received the second dose of GARDASIL (lot# not reported) on 25-JUN-2008 and then was given the third dose of GARDASIL (lot# not reported) on 13-OCT-2009. The physician reported that the patient did not have any experiences after receiving the other doses, but the patient believed they had a seizure because of GARDASIL. At the time of this report, the patient's outcome was unknown. Additional information has been received from the physician concerning the patient who on 22-APR-2008 was vaccinated with first dose of GARDASIL (lot# 660387/1967U). The patient then received the second dose of GARDASIL (lot# 660553/0070X) on 25-JUN-2008 and then was given the third dose of GARDASIL (lot# 660612/0229X) on 13-OCT-2009. The physician reported that the patient did not receive any concomitant vaccinations when she received the GARDASIL vaccinations. The patient's grandmother called the physician on 08-APR-2010 and reported that the patient was experiencing a seizure about once a month. The patient was seeing a neurologist. The physician did not consider the seizures to be disabling or life-threatening and the patient was not hospitalized. Upon internal review, seizure was considered to be an important medical event. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 4/22/2010 OB-GYN records for ovs 4/23/2008 and 10/13/2009 Vaccinations given, change in PMH: states dx'd with seizures. 5/5/2010 PCP ovs 11/07-3/19/2009, Dx seizures grandmother brought patient into MD office 3/19/09 stating patient has had seizure-like activity x 3, PCP referred patient to neurologist. 5/13/2010 Pediatric Neurology consult 7/27/2009, Dx epilepsy patient for evaluation of seizure activity x3, last seizure on 6/30/2009, fel

Other Meds: None

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. 4/22/2010 OB-GYN records for ovs 4/23/2008 and 10/13/2009 Labs: Ua wnl, HCG neg 5/5/2010 PCP ovs 11/07-3/19/2009, Dx seizures 5/13/2010

History: Unknown The following information was obtained through follow-up and/or provided by the government. 4/22/2010 OB-GYN records for ovs 4/23/2008 and 10/13/2009 5/5/2010 PCP ovs 11/07-3/19/2009, Dx seizures 5/13/2010 Pediatric Neurology consult 7/27/2009, Dx epilepsy PMH:seizure d/o Allergies: NKDA

Prex Illness: The following information was obtained through follow-up and/or provided by the government. 4/22/2010 OB-GYN records for ovs 4

Prex Vax Illns:

Vaers Id: 385592-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Dec-2007	31-Jan-2008	51	21-Apr-2010	22-Apr-2010	FR	WAES1004USA02225	23-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0253U	1	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Diabetes insipidus, No reaction on previous exposure to drug

Symptom Text: Case received from Health Authority on 12-APR-2010 (reference # PEI2010005944) : A 17 year old female on 04-OCT-2007 was vaccinated with the first dose of GARDASIL (lot # 1536F, batch # NG01520) which was well tolerated. On 11-DEC-2007 the patient received the second dose (IM, lot # 0253U, batch # NF58540) IM into the upper arm. On 31-JAN-2008 the patient was presented to a physician and diabetes insipidus was diagnosed which was confirmed by MRI and endocrinological examinations (not otherwise specified). The patient was treated ambulatory. Upon reporting form dated 02-MAR-2010 the patient had not recovered and "permanently damage" was ticked. Diabetes insipidus was considered to be disabling. Other business partner numbers included E2010-02328.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, diabetes insipidus was diagnosed; diagnostic laboratory test, endocrinological examinations : diabetes insipidus was diagnosed

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 385612-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Apr-2010	20-Apr-2010	0	21-Apr-2010	22-Apr-2010	NH	NH10	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Asthenia, Chills, Dizziness, Nausea, Pyrexia, Syncope

Symptom Text: Onset 6pm 4/20/10 chills, nausea, fever 103, dizziness, brief syncope in bathroom. Severe epigastric pain which lessened by 4/21/10 AM, weak, nausea 4/21/10 fever resolved by 4/21/10 AM.

Other Meds: OCP - ORTHO TRI CYCLEN

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

Vaers Id: **385624-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	19-Apr-2010	19-Apr-2010	0	21-Apr-2010	22-Apr-2010	MI		22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0968Y	0	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Gaze palsy, Musculoskeletal stiffness, Presyncope, Tremor

Symptom Text: I gave PT her first Gardasil injection, explained the risks and told her it our office polices for her to stay 20 mins after injection, she agreed. gave injection to LT buttocks she rolled over and her eyes rolled to back of her head, tightening her whole body and then a slight shake. I called out for DRs because they where closer to room. We watched patient for an hour. The Doctors explained that it was not a drug reaction, but overly excited reaction (Vasovagal). Patient was fine.

Other Meds:

Lab Data: no

History: No chronic problems noted, No medical conditions noted, Allergy to Codeine

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-Apr-2010	20-Apr-2010	0	21-Apr-2010	22-Apr-2010	KY		22-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1119Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Nodule, Skin warm

Symptom Text: 2 1/2 inch by 1 inch knot red, hot to touch.

Other Meds:

Lab Data:

History:

Prex Illness: Urinary tract infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385646-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Apr-2010	16-Apr-2010	0	21-Apr-2010	22-Apr-2010	CA		19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1316Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3061AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3353AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Hyperventilation, Muscular weakness, Myalgia, Pain, Paraesthesia

Symptom Text: On 4/16/10 pt received ADACEL, MENACTRA and GARDASIL, went home 2 Hrs later, she felt severe muscle body ache area UE, LE, trunk and chest and back. She complains of short of breath, tingling sensation of chest and back. She felt weakness of UE and LE. Not paralysis, No fever, she felt difficulty of breathing and tends to hyperventilate.

Other Meds: None

Lab Data: Seen at facility on 4/16/10 (-) lab test. Seen at hospital 4/17/10, Blood test, EKG, CXR, done all Normal

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385647-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Apr-2010	07-Apr-2010	0	21-Apr-2010	22-Apr-2010	MA		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1378Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash macular, Skin discomfort, Urticaria

Symptom Text: Patient received 1st dose of HPV. That night developed hives all over body - itchy & uncomfortable. BENADRYL given with some relief. After 2 weeks pt still has off & on splotchy skin - hive like reaction. Seems to flare up with exercise or in eve.

Other Meds: Multivitamin

Lab Data: None

History: None; N.K.D.A.

Prex Illness: Well Exam

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385683-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	09-Apr-2010	09-Apr-2010	0	22-Apr-2010	23-Apr-2010	FR	WAES1004CAN00004	25-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0946X	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Hypoaesthesia, Respiratory rate increased, Tachycardia

Symptom Text: Information has been received from a pharmacist concerning a 23 year old female who on 09-APR-2010 was vaccinated with the first dose of GARDASIL vaccine 0.5 mL, lot # 0946X. On approximately 09-APR-2010, the patient developed chest pain in middle of the chest radiating at on both sides, numbness on jaw and moved up to cheeks, fast breathing and tachycardia and was hospitalized. On approximately 09-APR-2010 the BP was 114/72 and pulse 88. Subsequently, the patient recovered from chest pain in middle of the chest radiating at on both sides, numbness on jaw and moved up to cheeks, fast breathing and tachycardia. Additional information has been requested.

Other Meds: Unknown

Lab Data: Blood pressure measurement, 09?Apr10, 114/72; Total heartbeat count, 09?Apr10, 88

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385717-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Apr-2010	20-Apr-2010	13	22-Apr-2010	23-Apr-2010	FL		26-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Pain in extremity, Paraesthesia

Symptom Text: PAIN TINGLING AND BURNING IN LEFT ARM DISTAL FROM ELBOW TO FINGERS ON THE LATERAL ASPECT. COMES AND GOES. YESTERDAY THERE WAS PAIN AND TINGLING IN HER RIGHT LEG FROM KNEES TO TOES MORE MEDIALLY. IT IS NOT CONTINUOUS OR "SEVERE". SHE WILL BE SEEN BY A NEUROLOGIST. IT IS TOO EARLY FOR ME TO PREDICT A COURSE OR EVEN KNOW FOR SURE IF THIS IS DUE TO THE VACCINE.

Other Meds:

Lab Data: NONE - AS ABOVE, THE PATIENT HAS BEEN REFERRED TO A NEUROLOGIST FOR FURTHER EVALUATION.

History: NO

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385729-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	25-Jan-2010	29-Jan-2010	4	22-Apr-2010	23-Apr-2010	FL		25-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Pyrexia

Symptom Text: Fever and headache that would not go away with medication. Dizziness. Given 1000 mg of Tylenol

Other Meds:

Lab Data: Hospital tested her for UTI, flu and mononucleosis. All tests were negative.

History: Aspergers

Prex Illness: Sinus infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385730-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Oct-2009	01-Oct-2009	0	22-Apr-2010	23-Apr-2010	CO		25-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3010AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336BA	1	Left arm	Intramuscular	
	HEP	MERCK & CO. INC.	1678X	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Pt reported only today that after her last vaccines (4) administered that day she developed severe hives over all her body

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **385751-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Oct-2009	01-Oct-2009	0	23-Apr-2010	26-Apr-2010	CO	WAES1004USA02811	26-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Facial palsy

Symptom Text: Information has been received for the pregnancy registry for GARDASIL from a physician concerning a 20 year old female patient, who in October 2009, "6 months ago", was vaccinated with the first dose of GARDASIL (route and lot number not provided). A couple of weeks after 1st dose, the patient got pregnant. The patient also developed Bell's Palsy after receiving the first dose but had a miscarriage sometime after developing Bell's Palsy. It was reported that the Bell's Palsy was getting better at the time of reporting. The patient's outcome regarding the miscarriage was unknown. The patient sought unspecified medical attention via office visit. Upon internal review, miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **385752-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		23-Apr-2010	26-Apr-2010	--	WAES1004USA03062	28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Biopsy brain abnormal, Blood glucose normal, Brain oedema, CSF glucose normal, CSF lactate normal, CSF oligoclonal band absent, CSF protein normal, CSF white blood cell count, CSF white blood cell count negative, Culture negative, Demyelination, Fundoscopy normal, Granulocyte percentage, Headache, Hemiparesis, Histology abnormal, Lymphocyte count increased, Lymphocyte percentage decreased, Macrophages increased, Mycobacterium test negative, Optic nerve disorder, Parasite blood test, Plasmapheresis, Pupillary deformity, Red blood cell sedimentation rate normal, Rheumatoid factor negative, Sensory loss, Toxoplasma serology, Vasogenic cerebral oedema, Visual acuity reduced, White blood cell count normal

Symptom Text: It was reported in a published article, title as stated above that a 16-year-old previously healthy girl presented 10 the emergency room with an acute onset of visual loss over 48 hours. Initially, there was visual loss noted in the right eye accompanied by a left side headache. These symptoms worsened over the next 24 hours to include visual loss involving the left eye with a more diffuse headache. When evaluated in the emergency room at 48 hours after onset, her vital signs were blood pressure 116/65, pulse 68/minute, respirations 14/minute, and temperature 98 degrees F, with a completely normal general physical examination and no signs of systemic illness. Her examination disclosed a visual acuity of only counting fingers bilaterally with mild left side weakness accompanied by sensory loss to pinprick in the left arm. There was a left afferent pupillary defect and normal fundoscopic examination. Her visual ability deteriorated further to inconsistently identifying light and movement from the left eye only. She complained of no other symptoms and denied antecedent trauma or prodromal illness. She had, however, received her second vaccination against human papilloma virus 10 days prior to her presentation. There was no family history of demyelinating disease, collagen-vascular disease, or rheumatological disorders. Magnetic resonance imaging (MRI) of the brain showed swollen enhancement within the chiasm extending into both retrobulbar optic nerves and a right occipitoparietal lobe mass (later disclosed as tumefactive demyelination) with a large zone of surrounding vasogenic edema. Complete spine MRI was normal. Biopsy of the hemispheric mass was performed and histology revealed demyelination. Subsequent cultures for aerobic and anaerobic bacteria, fungus, acid fast bacilli, and examination for parasites were negative as were serum immunoglobulin G and immunoglobulin M titers for Toxoplasma gondii. The erythrocyte sedimentation rate was 16 and the white blood cell count was 6900 with 89% granulocytes and 9% lymp

Other Meds: Unknown

Lab Data: magnetic resonance, brain-showed swollen enhancement-see narrative; blood pressure 116/65; diagnostic laboratory, Neuromyelitis optica-IgG-see narrative; pulse oximetry, 68/min; magnetic resonance, No new lesions; diagnostic microbiology, a

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **385753-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		23-Apr-2010	26-Apr-2010	--	WAES1004USA03165	26-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse reaction, Systemic lupus erythematosus

Symptom Text: Information has been received from a consumer concerning her daughter who on an unspecified date was vaccinated with a dose of GARDASIL. The consumer mentioned her daughter had a severe adverse reaction to GARDASIL and asked how people have reported lupus. At the time of the report, the outcome was unknown. Upon internal review, lupus was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **385754-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Mar-2010	30-Mar-2010	0	23-Apr-2010	26-Apr-2010	FR	WAES1004USA03226	26-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ28290	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy, Hypotonia, Immediate post-injection reaction, Muscle rigidity

Symptom Text: Information has been received from a health care professional concerning a 15 year old female patient. The patient was usually healthy. She had received the first dose of GARDASIL with no problems. The patient received the second dose of GARDASIL (batch number NK31480, lot number NJ28290, expiry in September 2010) in the left arm on 30-MAR-2010. On 30-MAR-2010, less than a minute post vaccination, the patient had a small fit. She went limp and her eyes rolled and then she went rigid. The patient recovered 1-2 minutes later. The patient's blood pressure was checked and was normal and she was examined by the doctor and there were no problems. The patient fully recovered on 30-MAR-2010 and was planning to receive the third dose. Small fit, went limp, eyes rolled and went rigid was considered to be an other important medical event. Other business partner numbers included: E2010-02489.

Other Meds: Unknown

Lab Data: blood pressure measurement, 30Mar10, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385777-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Apr-2010	16-Apr-2010	1	23-Apr-2010	23-Apr-2010	CA		25-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U30D6AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1316Y	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: Pt given MENINGOCOCCAL vaccine in right deltoid on Thursday 4/15/10 at 4 PM. On Friday 4/16 in PM - noticed upper arm, red, swollen & hot. Seen in clinic noon on Sat. 4/17. Given cold compress, told to repeat & take TYLENOL if needed.

Other Meds: None

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385779-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Apr-2010	13-Apr-2010	0	23-Apr-2010	23-Apr-2010	PA		26-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	U3042AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	00402	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Patient passed out after (GARDASIL) injection given.

Other Meds: None

Lab Data: Work up for syncope Blood test, EKG, C-T head are negative

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **385808-1 (S)** **Related reports:** 385808-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Dec-2008	06-Jan-2009	6	23-Apr-2010	26-Apr-2010	UT		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	3	Right arm	Unknown	MNQ

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Alopecia, Amnesia, Ataxia, Burning sensation, Conversion disorder, Deafness, Dizziness, Dyspnoea, Eating disorder, Erythema, Fatigue, Feeling cold, Gait disturbance, Headache, Hyperhidrosis, Hypersomnia, Hypoaesthesia, Menstruation irregular, Migraine, Muscle spasms, Muscular weakness, Nausea, Nervous system disorder, Neurological examination abnormal, Pain, Pallor, Palpitations, Paraesthesia, Phonophobia, Pyrexia, Rash, Rhinorrhoea, Screaming, Skin warm, Stress, Swelling, Tremor, Upper respiratory tract infection, Vision blurred, Weight decreased, Wrong drug administered

Symptom Text: Wrong shot given 12/26/08 (another meningitis shot given, instead of HPV #3). 1/6/09, upper respiratory infection, headache. 1/14/09 headaches worsen. Respiratory cleared up with antibiotics/looked like pneumonia. 1/15/09 dizziness. 1/28/09, headaches spike to levels 5-7 out of 10, 100% of the time. Ibuprofen does not work (800 mg). Mid feb: saw dr. Augmentum given for possible sinus infection. Headaches worsen, nasal fluid leakage continues. Augmentum does nothing. CAT scan MRI to be ordered within 5 days of Augmentum. Headaches spike to 7-8 100% of the time. Dizzy, no focus, loss of memory. Removed from school. Saw chiropractor - no one could touch the back of her head (meninga area) without her screaming. Says her head feels swollen and numb. Spine starts to burn. 2/15/09 8 pm, headaches go to 10/10, patient screaming. Consider possibility of brain tumor and take her to ER. Has trouble walking in straight line. CAT scan ordered by ER. Doctor send her home and tells her to take 2 Tylenols and 3 ibuprofens. CAT scan normal. 2/17 saw pediatrician again. Full blood work ordered: tests vitamin D, thyroid function, regular bloodwork. Referred to neurologist. 2/19/09 Dr. agrees problem could have been caused by cross reactions of Gardasil and Menactra: gives her Topomax at 50 mg/day and orders MRI. 2/20/09: MRI looks normal. Spine still burning, back of head untouchable, having more touble walking in a straight line. 2/23/09 2nd day of Topomax. Can only walk in 45 degree angles....cannot walk to bathroom. Go to ER, where she is seen by a team on neurologists and admitted to hospital for next 3 days. Ibuprofen administered via IV. No repsonse. 2nd day: DHE administered, which takes effect and after 3rd day she is released. March and April '09: patient can get through 2-4 hours of school each day and in the midst of that, needs a 1 hour rest on couch in office at school. Most days I pick her up at lunch. She is pale and very dizzy, with headaches reoccurring daily. Typically levels 4-5, with 7-8 spikes. She lose Th

Other Meds:

Lab Data: CAT scan, MRI, thyroid testing, bloodwork, heart monitoring The following information was obtained through follow-up and/or provided by the government. 4/26 and 5/5/2010 PCP records 12/2008, MR, for 2/23-2/25/2009, Neuro consult 4/3/2009,

History: CAPD (central auditory processing disorder) The following information was obtained through follow-up and/or provided by the government. 4/26 and 5/5/2010 PCP records 12/2008, MR, for 2/23-2/25/2009, Neuro consult 4/3/2009, Dx Migraines, Conversion disorder 5/18/2010 ED records for 2/16/2009, Dx headache 5/24/2010 chiropractor MR dx back pain 5/26/2010 MR for neuro consult 2

Prex Illness: none The following information was obtained through follow-up and/or provided by the government. 4/26 and 5/5/2010 PCP records 1

Prex Vax Illns:

Vaers Id: **385808-2 (S)** **Related reports:** 385808-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Dec-2008	26-Dec-2008	-5	14-Jun-2010	15-Jun-2010	--	WAES1005USA04222	15-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	3	Right arm	Unknown	MNQ

Seriousness: HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Activities of daily living impaired, Alopecia, Amnesia, Ataxia, Blood human chorionic gonadotropin negative, Blood test normal, Burning sensation, Cardiac monitoring, Computerised tomogram normal, Condition aggravated, Conversion disorder, Deafness, Dizziness, Dyspnoea, Eating disorder, Echocardiogram, Erythema, Fatigue, Feeling cold, Full blood count, Gait disturbance, Headache, Hyperaesthesia, Hyperhidrosis, Hypersomnia, Hypoaesthesia, Menstruation irregular, Migraine, Muscle spasms, Muscular weakness, Nausea, Nervous system disorder, Neurological examination abnormal, Pain, Pallor, Palpitations, Paraesthesia, Phonophobia, Pyrexia, Rash, Rhinorrhoea, Screaming, Skin warm, Stress, Swelling, Thyroid function test, Tremor, Upper respiratory tract infection, Vision blurred, Vitamin D, Wrong drug administered

Symptom Text: This report was identified from a line listing obtained on request by the company from the FDA under the Freedom of Information Act. A 14 year old female with conversion disorder and had an allergy of rash to red food dyes and a history of central auditory processing defect who on 31-DEC-2008 was vaccinated in right arm with a dose of GARDASIL (lot # 660616/0570X). Secondary suspected vaccination included a dose of MENACTRA. A 14 year old female experienced activities of daily living impaired, alopecia, amnesia, ataxia, burning sensation, conversion disorder, deafness, dizziness, dyspnoea, eating disorder, erythema, fatigue, feeling cold, gait disturbance, headache, hyperhidrosis, hypersomnia, hypoaesthesia, menstruation irregular, migraine, muscle spasms, muscular weakness, nausea, nervous system disorder, neurological examination abnormal, pain, pallor, palpitations, paraesthesia, phonophobia, pyrexia, rash, rhinorrhoea, screaming, skin warm, stress, swelling, tremor, upper respiratory tract infection, vision blurred and wrong drug administered. On 26-DEC-2008, the patient was given a wrong shot (another meningitis shot given, instead of the third dose of GARDASIL). On 06-JAN-2009, the patient experienced upper respiratory infection, headache. On 14-JAN-2009 headaches worsen. Respiratory cleared up with antibiotics/looked like pneumonia. On 15-JAN-2009, the patient experienced dizziness. On 28-JAN-2009, headaches spike to levels 5-7 out of 10, 100% of the time. Ibuprofen did not work (800 mg). In the middle of February: the patient saw doctor. AUGMENTIN was given for possible sinus infection. Headaches worsen, nasal fluid leakage continued. AUGMENTIN did nothing. CAT scan MRI to be ordered within 5 days of AUGMENTIN. Headaches spike to 7-8 100% of the time. Dizzy, no focus, loss of memory. The patient then removed from school. Saw chiropractor - no one could touch the back of her head (meninga area) without her screaming. Said her head felt swollen and numb. Spine started to burn. On 15-FEB-2009 at 8:00 pm, hea

Other Meds: Unknown

Lab Data: computed axial, 02/15/09, normal; magnetic resonance, 02/20/09, normal

History: Central auditory processing disorder

Prex Illness: Conversion disorder; Food allergy; Migraine

Prex Vax Illns:

Vaers Id: **385882-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	02-Jun-2009	02-Jun-2009	0	26-Apr-2010	27-Apr-2010	IL	WAES0907USA00225	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal heart rate decreased

Symptom Text: Information has been received from a healthcare worker concerning a 28 year old female patient with a history of miscarriages and no history of drug reactions/allergies who on 02-Jun-2009 was vaccinated IM with the first dose of GARDASIL (Lot #658271/0558X) 0.5ml. There were no concomitant medications. The patient was pregnant at the time of report. Her last menstruation period date is 28-Dec-2008 and her estimated delivery date is 04-Oct-2009. The patient has an irregular menstrual cycle and had a negative pregnancy test on 02-Jun-2009 before receiving GARDASIL (Lot #658271/0558X). There were no adverse effects reported. Additional information has been received as reported by the physician that the patient received the first dose of GARDASIL (Lot # 658271/0558X) on 02-Jun-2009 and before receiving GARDASIL (Lot # 658271/0558X) a pregnancy test was done but it came back negative. Then today 01-Jul-2009 the patient called the office and reported that she had taken a home pregnancy test and she was pregnant. The physician also reported that the patient has a history of miscarriages. No adverse effect involved. Follow up information has been received which stated that on an unspecified date the patient delivered a normal baby with no congenital anomaly, who on unspecified date experienced irregular heart rate and was hospitalized (WAES:0907USA00225B1). Follow up information has been received from an other health professional who reported that at 36 weeks of pregnancy the baby's heart rate was decreasing in the office so they sent the patient to the hospital. The patient had a C-section for the decreased heart rate. The baby's heart rate continued to be irregular and the child was sent to the hospital (WAES:0907USA00225B1). It was stated that this was the first mother's C-section of 13 pregnancies. The patient had 8 preemie babies. 2 full term babies and some miscarriages. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Miscarriage

Prex Illness: Pregnancy NOS (LMP = 12/28/2008); Irregular menstrual cycle

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385896-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Apr-2010	16-Apr-2010	0	26-Apr-2010	26-Apr-2010	AZ		27-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365CA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0819	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Immediate post-injection reaction, Nausea, Oropharyngeal pain, Pharyngitis streptococcal, Syncope, Vomiting

Symptom Text: Nausea - resolved. Fainted right after injection. Dizziness - intermittent. Vomiting 4/16/10 x 2 only. Fatigue - current. Headache sore throat > 4-17-10.

Other Meds:

Lab Data: Tested positive for strep pharyngitis

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385911-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Apr-2010	15-Apr-2010	3	26-Apr-2010	26-Apr-2010	FL		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash generalised, Rash maculo-papular

Symptom Text: Pt was tx for UTI on April 6th - SEPTRA BID x 5 days. Received GARDASIL vaccine on April 12th. On April 15th about 11pm pt complained of itching. Mother gave her BENADRYL. Presented to clinic AM of April 16th with raised maculopapular confluent rash generalized, was tx with ALLEGRA, Prednisone. No fever.

Other Meds: ALESSE

Lab Data: Quick strep screen negative - culture sent to lab at hosp.

History: Penicillin allergy

Prex Illness: None - received UTI

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385926-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Apr-2010	22-Apr-2010	1	26-Apr-2010	26-Apr-2010	AR		29-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3018AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3356AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0075Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site warmth

Symptom Text: Area of redness with local temp increased 3 cm x 2 cm R upper arm where MENACTRA was given.

Other Meds: None

Lab Data: None

History: None

Prex Illness: Scabies; Migraines; Sore throat

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385953-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Apr-2010	22-Apr-2010	2	26-Apr-2010	26-Apr-2010	PA		27-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB345BA	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3088A	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1298Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0229X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site haemorrhage, Injection site swelling

Symptom Text: Swelling, ecchymosis at site of vaccination - Upper left arm - (deltoid).

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **385977-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	M	26-Apr-2010	26-Apr-2010	0	26-Apr-2010	27-Apr-2010	AR		28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3356AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1332Y	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1647Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope.

Other Meds: None

Lab Data: None

History: None

Prex Illness: Allergic rhinitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386010-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Apr-2010	15-Apr-2010	0	27-Apr-2010	27-Apr-2010	MO	MO-2010-06	28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1379Y		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1318Y		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dysstasia, Feeling abnormal, Pain in extremity, Rash, Rash papular, Tremor

Symptom Text: Received Gardasil and Hepatitis A. Hour after getting right arm tremors, couldn't stand up. States lasted all day. Head felt empty, felt weird. Next day better but still dizzy and hand haking. Able to work, complaints of bumps on chest. 4-19-10 right arm still sore. complaints of face breaking out. thinks it's Gardasil

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386018-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		27-Apr-2010	28-Apr-2010	--	WAES1004USA02810	28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse concerning a female patient who was vaccinated with "all three doses" of GARDASIL. The nurse reported that she saw on local news channel that the mother of the patient experienced seizures after receiving three doses of GARDASIL. The nurse stated that the patient's seizures were linked to GARDASIL vaccine. The patient was diagnosed with a seizure disorder. The nurse did not know the patient's recovery status and did not know the patient's identifiers. Upon internal review, seizures was considered an other important medical event. Additional information is not expected.

Other Meds: unknown

Lab Data: unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **386019-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Dec-2009	21-Dec-2009	1	27-Apr-2010	28-Apr-2010	NM	WAES1004USA03337	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960F	1	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B014BA		Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Electrocardiogram ambulatory, Grand mal convulsion, Headache, Neurological examination normal, Personality change, Petit mal epilepsy, Presyncope, Speech disorder, Syncope

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who "4 months ago", on approximately 20-DEC-2009, received the first dose of GARDASIL (Lot # not reported) from her pediatrician. The patient also received 3 other unspecified vaccines on the same day. It was reported that within 24 hours of administration of GARDASIL, the patient began experiencing seizures (petit mal and grand mal) along with personality changes. At the time of the report the patient was still experiencing petit mal seizures. The patient had been evaluated by several specialists, but no abnormal findings had been identified to the time of the report. Diagnostic laboratory tests included "blood work" (negative). Upon internal review seizures (petit mal and grand mal) were considered to be other important medical event. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 5/13/2010, Ed records for 3/8/2010, Dx recurrent syncopal episodes 5/24/2010 ED neuro consult for 1/26/2010, DX ? partial complex seizure, ? migraine patient sent per PCP to this ER for a "2nd opinion", had been having numerous sx, being evaluated per cardiology for suspected vasovagal episodes, Holter monitor test results are not available, neuro exam was wnl, per neurologist a definitive dx could not be made

Other Meds: Unknown

Lab Data: diagnostic laboratory, negative The following information was obtained through follow-up and/or provided by the government. 5/13/2010, Labs/dx studies for 3/8/2010, Dx recurrent syncopal episodes 5/24/2010 ED neuro consult for 1/26/2010,

History: Unknown The following information was obtained through follow-up and/or provided by the government. 5/13/2010, Labs/dx studies for 3/8/2010, Dx recurrent syncopal episodes 5/24/2010 ED neuro consult for 1/26/2010, DX ? partial complex seizure, ? migraine PMH: None Allergies: NKDA

Prex Illness: The following information was obtained through follow-up and/or provided by the government. 5/13/2010, Labs/Dx studies 3/8/201

Prex Vax Illns:

Vaers Id: 386020-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	20-Apr-2009	07-Jun-2009	48	27-Apr-2010	28-Apr-2010	NJ	WAES0908USA00845	28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1702X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Cephalo-pelvic disproportion, Drug exposure during pregnancy, Umbilical cord around neck

Symptom Text: Information has been received from a medical assistant, for GARDASIL, a Pregnancy Registry product, concerning a 24 year old female patient with no pertinent medical history and no known allergies who on. On 22-JUN-2009 the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot number 0294Y). There was no concomitant medication. On an unspecified date, the patient was determined to be pregnant by a urine pregnancy test. The last menstrual period (LMP) was 07-JUN-2009 and the estimated delivery date (EDD) was 15-MAR-2010. Medical attention was sought in the office (date unspecified). On 06-AUG-2009, the patient had an ultrasound to confirm dating results were reported as within normal limits (WNL). Follow-up information has been received from the medical assistant concerning the female patient with a history of one elective termination (date unspecified) who on 20-APR-2009 was vaccinated with the first dose of GARDASIL (lot number 1702X). On 02-SEP-2009 an "ultrascreen" was performed in order to rule out early detection of DOWN syndrome, Trisomy 18/13. The result of the test was within normal limits. Additional information has been requested. Information has been received from a medical assistant, for GARDASIL, a Pregnancy Registry product, concerning a 24 year old female patient with no pertinent medical history and no known allergies who on. On 22-JUN-2009 the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot number 0294Y). There was no concomitant medication. On an unspecified date, the patient was determined to be pregnant by a urine pregnancy test. The last menstrual period (LMP) was 07-JUN-2009 and the estimated delivery date (EDD) was 15-MAR-2010. Medical attention was sought in the office (date unspecified). On 06-AUG-2009, the patient had an ultrasound to confirm dating results were reported as within normal limits (WNL). Follow-up information has been received from the medical assistant concerning the female patient with a history of one elective termination (date uns

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 08/06/09, within normal limits; ultrasound, 09/02/09, within normal limits; urine beta-human, pregnant

History: Termination of pregnancy - elective

Prex Illness:

Prex Vax Illns:

Vaers Id: **386033-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Apr-2010	Unknown		27-Apr-2010	27-Apr-2010	CA		28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Arthralgia, Asthenia, Oral herpes

Symptom Text: Fever blister on lip, feeling weak, upset stomach, achy joints hurt.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386063-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Mar-2010	10-Apr-2010	17	27-Apr-2010	27-Apr-2010	NY		28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3030AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eyelid function disorder, Facial palsy, Paraesthesia

Symptom Text: Patient presented to ED with Right sided facial droop and difficulty opening eye lids. Stating " right side of face not working." She was diagnosed in ED with Bell's Palsy

Other Meds:

Lab Data: Negative Lyme titer

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386065-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Apr-2010	21-Apr-2010	0	27-Apr-2010	28-Apr-2010	LA		29-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1332Y	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Mouth ulceration, Oral pain

Symptom Text: Big ulceration the Rt buccal mucosa, painful, tender, small Rt submandibular gland.

Other Meds: ALEVE

Lab Data: CBC

History:

Prex Illness: Not ill

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386095-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Apr-2010	23-Apr-2010	0	27-Apr-2010	28-Apr-2010	CA		28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	11784	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bradycardia, Immediate post-injection reaction, Syncope

Symptom Text: Patient had witnessed syncopal episode immediately following vaccine. Patient was assessed and was bradycardic (40 BPM) and blood pressure was not able to be auscultated or palpated. Patient was questioned immediately following and was conscious and oriented but was persistently bradycardic. Patient then had a second witnessed syncopal episode at 10:55 AM and she remained bradycardic for several more minutes. Patient began to recover and at 11:012 AM her pulse was 58 BPM and blood pressure was 88/48. Her SPO2 remained 100% throughout the entire episode. Patient was never post-ictal and never had any convulsions or seizure activity.

Other Meds: Orthotricyclen-LO

Lab Data: EKG was done that showed heart rate of 38, with regular ventricular rate but sufficient artifcat to obscure any p waves. No ectopy was noted. Patient received further work-up at the Er to include urine pregnancy test, CBC, BMP, Coags and Ch

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **386098-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	22-Apr-2010	25-Apr-2010	3	27-Apr-2010	28-Apr-2010	PA		29-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Lymph node pain, Lymphadenopathy, Thrombosis

Symptom Text: Swelling at injection site about the size of a pencil eraser (normal), then continued to grow throughout Sunday and Monday to the size of a very large grape. Monday my armpit lymph node became swollen and very painful. Saw the doctor Tuesday and she explained there was a clot of blood that has built up in my arm and that I needed to keep warm compresses on it in hopes of it breaking up.

Other Meds: Birth Control

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **386099-1 (S)** **Related reports:** 386099-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Jul-2009	30-Sep-2009	69	27-Apr-2010	28-Apr-2010	IN		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Back pain, Disturbance in attention, Fibromyalgia, Headache, Hypoaesthesia, Induration, Insomnia, Joint range of motion decreased, Ligament sprain, Mobility decreased, Muscle spasms, Muscular weakness, Pain, Swelling

Symptom Text: Fibromyalgia symptoms: excruciating pain-back, chest, neck, arms, hips and legs, headaches, muscle weakness, generalized swelling-all over body, muscle knots, muscle spasms, insomnia, difficulty concentrating, limited mobility, limited range of motion. Symptoms started in Sept 2009, at onset was mainly back pain with symptoms progressively worsening to date. Treatment -Oct 2009, diagnosed with thoracic sprain, pain med and prednisone prescribed. Primary care physician, Oct 29, 2009- ordered Mobic, Lortab, and Flexeril. Nov 11,2009 Dr -stopped Mobic and Flexeril and ordered Zanaflex and ibuprofen. Also ordered physical therapy. -started 11/12/2009. After several sessions stopped physical therapy due to increasing pain and inability to tolerate therapy. 11/25/09 MRI - cervical and lumbar. Several weeks of chiropractic care- stopped due to inability to tolerate and not improving. Spine clinic- Dr evaluated and referred. 12/16/09 Rehab -Several visits - trigger point injections, lidocaine patches, nortriptyline, Lexapro-no improvement. Psychologist-psych eval. - started in March 2010-Has tried several meds without success- Diagnosed with fibromyalgia and referred to another Dr. April 19, 2010, 1st appt with Dr and fibromyalgia diagnosis confirmed. Patient is taking several medications to try to help control symptoms-Neurontin, Savella, Klonopin, and Ultram but so far still no improvement. She still remains in excruciating uncontolled pain along with increasing weakness, generalized swelling, muscle knots, muscle spasms, insomnia, difficulty concentrating, limited mobility and limited range of motion. The following information was obtained through follow-up and/or provided by the government. 4/28, 4/29 and 4/30/2010, Op rehab summary 11/12-11/23/2009, Urgent care clinic visit 10/22/2009, PCP ovs 10/29-11/19/2009, OP PT evaluation 11/12/2009 and MR, Adult Rehab MR 12/16/2009, Pain clinic ov 4/19/2010, Ortho spine MD ov's 3/1-4/19/2010, Dx fibromyalgia c/o's upper and lower back pain with bilateral UE pain and numbne

Other Meds: Yaz

Lab Data: Lab tests: CBC, BMP, Sed Rate, creatine, CBC, CMP, A/G ratio, Bilirubin, alkaline phosphatase, AST, ALT, CORTISOL, RHEUMATOID ARTHRITIS, SED RATE, LYME. Also MRI performed- cervical and thoracic. The following information was obtained throu

History: None. The following information was obtained through follow-up and/or provided by the government. 4/28, 4/29 and 4/30/2010, Op rehab summary 11/12-11/23/2009, Urgent care clinic visit 10/22/2009, PCP ovs 10/29-11/19/2009, OP PT evaluation 11/12/2009 and MR, Adult Rehab MR 12/16/2009, Pain clinic ov 4/19/2010, Ortho spine MD ov's 3/1-4/19/2010, Dx fibromyalgia PMH: None Allergies

Prex Illness: None. The following information was obtained through follow-up and/or provided by the government. 4/28, 4/29 and 4/30/2010, Op r

Prex Vax Illns:

Vaers Id: **386099-2 (S)** **Related reports:** 386099-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Jul-2009	Unknown		28-Jun-2010	29-Jun-2010	IN	WAES1005USA01031	29-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Back pain, Blood test, Chest pain, Disturbance in attention, Fibromyalgia, Headache, Impaired driving ability, Impaired work ability, Injection site pain, Insomnia, Joint range of motion decreased, Ligament sprain, Mobility decreased, Muscle disorder, Muscle spasms, Muscular weakness, Neck pain, Pain, Pain in extremity, Swelling, Wheelchair user

Symptom Text: Information has been received from a nurse concerning her 19 year old daughter with allergy to PERCOCET (had rash and itching) who on 23-JUL-2009 and 24-SEP-2009, was vaccinated with the first and second dose of GARDASIL (lot # 659964/1978U for dose 1, 661531/1311X for dose 2) IM into her left arm. Concomitant therapy included YAZ. The patient did not receive other vaccinations. On an unspecified date, the patient had complained that the shots were very painful at the injection site. Then by the end of September, the patient complained of back pain. On 22-OCT-2009, the patient was taken to an Urgent Care Center and was diagnosed with thoracic sprain. She was treated with pain medications and prednisone. On 29-OCT-2009, the patient was seen by a physician, her primary healthcare professional (HCP) at the time and was treated with MOBIC, cyclobenzaprine hydrochloride and LORTAB. On follow up visit of 11-NOV-2009, the physician recommended physical therapy and added ZANAFLEX and ibuprofen. The patient experienced fibromyalgia. On 12-NOV-2009, the patient went to another place for outpatient therapy. Stopped therapy made her feel too much pain. On 25-NOV-2009, priority radiology magnetic resonance imaging (MRI) was performed on thoracic, cervical and lumbar, and nothing was found. Then the patient went to chiropractor but stopped due to too much pain. The patient went to a spine Institute with another physician, and nothing was found. Then the patient was sent to an Associates on 16-DEC-2009 and was given lidocaine patches, and trigger point injections for muscle knots in neck and back. Other Medications included LEXAPRO and nortriptyline. On 30-DEC-2009, 06-JAN-2010 and 03-FEB-2010, the patient had other visits to this facility, but no improvement. The patient was seen at the place for outpatient therapy again for psychological evaluations one time, but did not return. In March 2010, the patient was seen by another physician as her primary care physician. In April 2010, she went to a hospital emergency room with "ex

Other Meds: YAZ

Lab Data: Magnetic resonance, 11/25/09, thoracic, cervical and lumbar: nothing was found

History: Rash; Pruritus

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386100-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	19-Apr-2010	19-Apr-2010	0	27-Apr-2010	28-Apr-2010	TN		28-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1333Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Dyspnoea, Pruritus

Symptom Text: Tightness in chest, "difficulty breathing," which was present in the evening but resolved in the morning. In the evening she also began developing pruritus over her entire body and small bumps where she feels the pruritus.

Other Meds: Centrum 1 tablet by mouth daily Chromium 350mcg 1 tablet by mouth daily One Touch Ultra Test Strips use 2x daily to test blood sugar ICD-9 250.00 Levothyroxine 300 mcg Tab 1 tablet by mouth every morning ? [(filled 4/12/2010)] Lisinopri

Lab Data: None, patient taking Benadryl, Pepcid, Rx given for EpiPen, referral for allergy testing. I will continue to monitor her until her pruritus resolves.

History: Hypothyroidism (TSH=16.3 on 3/10/2010) Diabetes --nephropathy HTN w/ CRI Anemia Body cramps ("due to thyroid") UTI's PCOS --Hirsutism --Polycystic ovaries on ultrasound 3/2010 Menorrhagia --Thickened endometrial stripe on ultrasound 3/2010

Prex Illness: None known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386106-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Apr-2010	27-Apr-2010	1	27-Apr-2010	28-Apr-2010	KY		29-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Vomiting

Symptom Text: Vomiting x 3, site swelling 80 mm in size.

Other Meds:

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386142-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	M	28-Apr-2010	28-Apr-2010	0	28-Apr-2010	28-Apr-2010	TX		28-Apr-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MEN	SANOFI PASTEUR	U3054AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0075Y	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1133Y	1	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB342AA	0	Left arm	Intramuscular	
FLU(H1N1)	SANOFI PASTEUR	UP050AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Dyspnoea, Erythema, Eye swelling, Oxygen saturation decreased

Symptom Text: Difficulty Breathing, low oxygen saturation, cough, eye swelling, facial redness.

Other Meds: Concerta, Strattera, Singulair, Claritin, Nasonex

Lab Data:

History: ADHD, Asthma, Allergic Rhinitis

Prex Illness: none

Prex Vax Illns:

Vaers Id: **386158-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Mar-2010	10-Mar-2010	0	28-Apr-2010	29-Apr-2010	AZ	WAES1004USA03702	26-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	3	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Blepharospasm, Convulsion, Fatigue, Feeling cold, Incorrect route of drug administration, Injection site pain, Loss of consciousness, Narcolepsy, No reaction on previous exposure to drug, Pyrexia, Syncope, Tinnitus, Vision blurred

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on 21-JUL-2009, 22-OCT-2009 in the left arm and on 10-MAR-2010 (lot # 661530/1575X) was vaccinated with the first, second and third 0.5 ml doses respectively of GARDASIL. On 21-JUL-2009, the patient was vaccinated with the second dose of VARIVAX (Merck) and on 22-OCT-2009 a dose of intranasal FLUMIST "in different arm". It was reported that the patient experienced injection site pain and fever up to 101 degrees after getting the third dose of GARDASIL on 10-MAR-2010. On 31-MAR-2010, the patient experienced tiredness, pain in her knee, complaint of fainting, 30 seconds of eye twitching, her body felt cold and ringing in her ears. On 18-APR-2010, the patient experienced 45 seconds of blurred vision to black out, eyes twitching, seizures and ongoing severe fatigue. The physician suspected that it could be Narcolepsy. The patient sought unspecified medical attention. At the time of the report the adverse events reported as not improved and the patient's present status was reported as unspecified. Upon internal review seizures were determined to be other important medical event. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 5/4 and 5/7/2010 PCP ov 4/19/2010 Dx ? possible seizures patient with c/o's feeling faint episodes, ears ringing, eyes twitch, felt cold, blurred vision, fatigue, fever and joint pain, mother felt due to vaccination (Gardisil) although patient did not have adverse reaction after first 2 injections

Other Meds:

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. 5/4 and 5/7/2010 PCP ov 4/19/2010 Dx ? possible seizures Labs: CBC, CMP, TFT's, Antithyroid AB, ANA and RA (no results noted) Dx studies: n

History: Unknown The following information was obtained through follow-up and/or provided by the government. 5/4 and 5/7/2010 PCP ov 4/19/2010 Dx ? possible seizures PMH: scoliosis Allergies: NKDA

Prex Illness: The following information was obtained through follow-up and/or provided by the government. 5/4 and 5/7/2010 PCP ov 4/19/2010

Prex Vax Illns:

Vaers Id: **386190-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	20-Apr-2010	26-Apr-2010	6	28-Apr-2010	29-Apr-2010	AR		01-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0075Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling

Symptom Text: RUA --> GARDASIL - Site IM given area of swelling and redness and mild itching 2cm x 2cm.

Other Meds:

Lab Data: None

History: A Rhinitis; Asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386195-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Apr-2010	23-Apr-2010	2	29-Apr-2010	29-Apr-2010	GA		11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash erythematous

Symptom Text: GARDASIL vaccine dose # 2 given 4-21-10 (Had dose # 1 7/20/07) - pt. returned to office 4/26/10 with rash (red, itching) on both arms, elbow, legs, top of (R) foot, back. - Tx w/ BENADRYL.

Other Meds: None

Lab Data: Idiopathic urticaria vs reaction to HPV GARDASIL

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **386203-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Apr-2010	17-Apr-2010	2	29-Apr-2010	29-Apr-2010	TX	TX20100016PU	20-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1445Y	1	Right arm	Subcutaneously	
MEN	SANOFI PASTEUR	U3054AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3352AA	4	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0928U	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB342AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Hypersensitivity, Swelling face, Temperature intolerance, Urticaria

Symptom Text: PATIENT BROKE OUT IN HIVES ALL OVER HER BODY ON 4/7 AND BENADRYL GIVEN EVERY 6 HOURS. TODAY SHE WOKE UP WITH HER FACE SWOLLEN AND TOLD HER FATHER THAT SHE FELT LIKE SOMEONE WAS STANDING ON HER CHEST. I ADVISED THE FATHER TO TAKE HER TO THE ER IMMEDIATELY. ON 4/12, I CALLED THE FATHER TO CHECK ON PATIENT. HE REPORTED THAT HE TOOK HIS DAUGHTER TO THE ER AT MEDICAL CTR AND THE PHYSICIAN AT THE HOSPITAL TOLD HIM THAT SHE HAD AN ALLERGIC REACTION TO THE HPV VACCINE. THE PHYSICIAN TOLD HIM TO CONTINUE BENADRYL. ON 3/31 PATIENT WAS TREATED FOR STREP THROAT AND WAS GIVEN AMOXICILLIN. SHE WAS STILL ON THE TREATMENT WHEN THE VACCINE WAS GIVEN. HE REPORTED THAT HE HAD TOLD THE PHYSICIAN ABOUT THE TREATMENT FOR STREP THROAT. THE FATHER REPORTED THAT THE SWELLING TO HIS DAUGHTER'S FACE SUBSIDED BY SATURDAY 4/10. THE HIVES SUBSIDED BY THE NEXT DAY. HE STATES SHE IS STILL SENSITIVE TO HEAT. I TOLD THE FATHER I WOULD REPORT THIS TO MEDICAL DIRECTOR FOR ADVICE ON GIVING FOLLOWUP VACCINES. DR ADVISED TO GIVE FOLLOWUP VACCINES ON SEPARATE VISITS AND GIVE BENADRYL FOR REACTION.

Other Meds: AMOXICILLIN

Lab Data: NONE

History: STREP THROAT 3/31/10 TREATED WITH ANTIBIOTIC AMOXICILLIN.

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386228-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	13-Oct-2009	20-Oct-2009	7	29-Apr-2010	30-Apr-2010	FR	WAES1004USA03510	30-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eyelid disorder, Oral pain, VIIth nerve paralysis

Symptom Text: Information has been received from a physician concerning a 10 year old female patient who on 13-OCT-2009 was vaccinated with the first dose of GARDASIL. Concomitant therapy included a dose of TWINRIX. One week later, on approximately 20-OCT-2009 the patient experienced paralysis of the 7th cranial nerve, mouth deviation and elevated eyelid. Those events lasted 1 month. At the emergency room, the physician told the patient's parents that the patient possibly had Bell's Palsy. It was unknown if paralysis of the 7th cranial nerve, mouth deviation and elevated eyelid were related to therapy with GARDASIL. Upon internal review, paralysis of the 7th cranial nerve was considered to be an other important medical event. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 386231-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Mar-2010	06-Apr-2010	7	29-Apr-2010	30-Apr-2010	FR	WAES1004USA03240	30-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Fatigue, Infectious mononucleosis, Lymphadenopathy, Malaise, Nausea, Pyrexia, Vomiting

Symptom Text: Case reported from a health care professional under the reference number RA-078-2010. A 17-year-old female patient received the first dose of GARDASIL (batch number, site of administration and route not reported) on 30-MAR-2010. One week post vaccination (approximately on 06-APR-2010), the patient presented with fever, cervical lymphadenopathy, nausea, vomiting, general malaise, fatigue that have finished on unspecified date. The patient went to the primary care physician and he had requested complementary tests. As the result of analytical exams were very high (not otherwise specified), the patient was hospitalized on 13-APR-2010 and discharged on 14-APR-2010 with a prescription of BEN-U-RON (also reported as concomitant therapy) to be used in case of fever. The preliminary diagnosis was viral hepatitis. However, the nurse was informed by the patient's mother that the diagnosis of viral hepatitis was ruled out at the hospital. The final diagnosis was mononucleosis and, according to the reporter it was not related with the vaccine. The patient had recovered on an unspecified date. No further information is available. Other business partner numbers include E2010-02518.

Other Meds: Unknown

Lab Data: laboratory test, ??Apr10, complementary test: the results of analytical exams were very high

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **386249-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Sep-2008	12-Sep-2008	3	29-Apr-2010	30-Apr-2010	NC	WAES1004USA03558	30-Apr-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion, Henoch-Schonlein purpura, Skin discolouration

Symptom Text: Information has been received from a physician concerning a 15 year old female patient, who on 09-SEP-2008, was vaccinated with the first dose 0.5 mL dose of GARDASIL vaccine (route and lot number not provided). On 12-SEP-2008, the patient experienced purple bruising around the legs and ankles. The patient went to an infectious disease specialist and was diagnosed with Henoch-Schonlein purpura (HSP) (form of purpura). It was reported that therapy with GARDASIL was discontinued and the patient received only the first dose. The patient's outcome was unknown at the time of reporting. The patient sought medical attention through an infectious disease specialist. Upon internal review, Henoch-Schonlein purpura was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386254-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	M	21-Apr-2010	22-Apr-2010	1	29-Apr-2010	29-Apr-2010	WI		13-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	SANOFI PASTEUR	43097AA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1537Y	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye pain, Fatigue, Sensation of heaviness

Symptom Text: Mother called to report pt woke up 4-22-10 8 AM with "pain" to eyes and both legs felt like lead and fatigue. Reviewed VIS. Advised mother to take pt to see healthcare provider this AM. Will call her back 4/27/10.

Other Meds: None known

Lab Data:

History: None known

Prex Illness: None known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386317-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Apr-2010	06-Apr-2010	0	30-Apr-2010	30-Apr-2010	AZ		04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1538Y	1	Right arm	Unknown	
	MEN	SANOFI PASTEUR	U3061AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3356AA	5	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1013Y	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Dizziness, Feeling cold, Hyperaesthesia, Tremor

Symptom Text: Approx 20 min after receiving injections, pt c/o feeling dizzy. No SOB no diaphoresis, however, status change noted. Pt unable to answer questions. No LOC. Hypersensitive to touch on arms. EMS called. BP 118/68. Glucose 73. Pt c/o feeling cold and shaking/shivering observed. Transported to Emergency Room via ambulance 30 min after injections given.

Other Meds: None

Lab Data: Blood tests; Urine; X-R; EKG, all reported "normal" per mom.

History: None reported by mother

Prex Illness: None reported by pt. and mother

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386336-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	22-Apr-2010	27-Apr-2010	5	30-Apr-2010	30-Apr-2010	CO		19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	
	MEN	SANOFI PASTEUR	U2933AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site swelling

Symptom Text: Notes itchy swollen R upper arm on R. (site of HPV and Menactra vaccines) and smaller area on L upper arm (TDAP site).

Other Meds:

Lab Data:

History: Hx is seizures

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	28-Dec-2009	28-Dec-2009	0	30-Apr-2010	03-May-2010	IL	WAES1004USA03774	03-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Haemorrhage

Symptom Text: Information has been received from a registered nurse as part of the pregnancy registry for GARDASIL, concerning a 24 year old Rh negative female patient with no known drug allergies, history of 4 pregnancies: 3 elective abortions (no dates provided), 1 live birth and a LEEP procedure on 07-DEC-2009 who "elsewhere about 3 years ago" was vaccinated with the first dose of GARDASIL and on 12/28/2009 was vaccinated with the second dose of GARDASIL (Lot# 663454/0672Y). The patient had an "UCG" test positive at home, an ultrasound was performed on 22-APR-2010 and showed a nonviable pregnancy. The nurse reported that the patient started bleeding on 22-APR-2010 (also reported as mid April) and was diagnosed with a spontaneous abortion. LMP: 12-FEB-2010; estimated due date 19-NOV-2010. The products of conception were examined in the office but not sent to the lab The event was not considered disabling or life threatening; there was no hospitalization. The patient had recovered. Upon internal review spontaneous abortion was considered to be other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 04/22/10, showed a nonviable pregnancy; beta-human chorionic, positive, at home

History: Loop electrosurgical excision procedure

Prex Illness: Pregnancy NOS (LMP = 2/12/2010); Rhesus antibodies negative

Prex Vax Illns:

Vaers Id: **386345-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Feb-2009	01-Feb-2009	0	30-Apr-2010	03-May-2010	FR	WAES1004USA03806	26-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Encephalitis, Incorrect route of drug administration

Symptom Text: Information has been received from the Health Authorities under the reference numbers CN20100207 and CN090047. A 20 year old female patient experienced an encephalitic reaction after she had received a subcutaneous injection of GARDASIL (batch number not reported) on 01-FEB-2009. The case was identified as a misuse (incorrect route of administration), although not reported as such by the HA: the recommended route for GARDASIL was the intramuscular one. The patient had no relevant personal medical history. A few days after vaccination, the patient experienced an encephalitic reaction and was hospitalized. CT angiography, brain CT scan and MRI scan were normal. The patient recovered on 12-FEB-2009. The health authorities assessed the causal relationship between the reported reaction and the vaccination as (doubtful) (C1 S1 L1) according to the foreign method of assessment. The seriousness criterion reported by the HA was hospitalization. The HA coded the event of encephalitic reaction. Other business partner included E2010-02626. No further information is available.

Other Meds: Unknown

Lab Data: angiography, normal; head computed axial tomography, normal; magnetic resonance imaging, normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 386347-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-Jul-2008	28-Dec-2008	166	30-Apr-2010	03-May-2010	MO	WAES1004USA03907	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Anaemia, Arthritis, Echocardiogram normal, Gait disturbance, Haematuria, Iron deficiency, Joint swelling, Liver function test abnormal, Local swelling, Lymphadenopathy, Musculoskeletal stiffness, Myositis, Neck pain, Night sweats, Oedema peripheral, Oropharyngeal pain, Pain in extremity, Pericardial effusion, Pruritus, Pyrexia, Rash, Rash papular, Septic rash, Ultrasound Doppler normal, Urinary tract infection

Symptom Text: Information has been received from a laboratory technician, concerning her 19 year old daughter, with no pertinent medical history and no known drug allergies, who on 08-JAN-2008, was vaccinated with the first dose of GARDASIL (dose and route not provided) (lot number 659657/1487U). On 06-MAR-2008, the patient received the second dose of GARDASIL (dose and route not provided) (lot number 659657/1487U). On 15-JUL-2008, the patient received the third dose of GARDASIL (dose and route not provided) (lot number 660389/1968U). Concomitant therapy included hormonal contraceptives (unspecified). There were not concomitant vaccines administered. On 28-DEC-2008, the patient experienced neck stiffness which eventually became a swollen neck. On approximately 08-JAN-2009, "after the first week and a half", the patient had night sweats with a fever. On 15-JAN-2009, "a week after the nights and fever" the patient broke out with a septic rash on her legs, then went to urgent care. On 15-JAN-2009, the patient got a computed axial tomography scan on her neck and found enlarged lymph nodes. On 16-JAN-2009, the patient got a computed axial tomography scan of the abdomen and showed enlarged lymph nodes and pericardial "infusion". On 26-JAN-2009, "the end of January", the patient was hospitalized for 5 days because her left leg was swollen and the patient could not walk on it. The patient's feet and toes were swollen as well. On 27-JAN-2009, the patient ended up having an ultrasound (also reported as sonogram) of the left leg, and showed swelling but no blood clots. On 30-JAN-2009, the patient had a magnetic resonance imaging of the ankle and calf and the result was negative. The patient was also tested for Guillain-Barre and Epstein-Barr virus and both were negative. Prescription treatment included pain medications (unspecified), steroids (unspecified) and antibiotics (unspecified). The patient sought chiropractic care and was seen by a rheumatologist. No diagnosis was made. On an unknown date, the patient initiated a peripherally in

Other Meds: Hormonal contraceptives

Lab Data: computed axial, 01/15/09, in neck: enlarged lymph nodes; abdominal computed, 01/16/09, enlarged lymph nodes and pericardial "infusion"; ultrasound, 01/27/09, swelling in left leg; magnetic resonance, 01/30/09, ankle and calf: negative; labo

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386385-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Apr-2010	08-Apr-2010	1	30-Apr-2010	03-May-2010	PA		12-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3355BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1099Y	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1684Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Pain in extremity, Pyrexia

Symptom Text: Within 24 hours, pain in arm, dizzy, headache, fatigue, fever 100.9. Seen in office - ED - back in office. Labs are normal.

Other Meds:

Lab Data: CBC; CMP; CRP; TSH: all normal

History: Rotator cuff - shoulder pain; Migraines; Asthma; Joint pains

Prex Illness: None known

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386387-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Apr-2010	29-Apr-2010	0	30-Apr-2010	03-May-2010	AZ		07-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle twitching

Symptom Text: Twitching of left eye.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386391-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	M	01-May-2010	01-May-2010	0	30-Apr-2010	03-May-2010	AZ		05-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U3044AA	0	Unknown	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041BA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphasia, Cold sweat, Pallor

Symptom Text: 10:12 - Received 3 vaccines, TDAP, MCVY, HPV in that order - stopped talking and got pale, head lowered it protected safely in chair. LOC x about 15 sec, clammy cool cloth behind neck. Mom at side entire time during shot-went outside with daughter. Order-protect in chair x 5 min more. Mom gave water and power bar talking with us, sat in lobby x 10 more min, took 2nd 16 oz of water. Left ambulatory with mom and sister - encouraged to rest, eat and drink. Call ped if need or go to ER. Verbalized OK-1205 call placed to Mom's cell LMOM to call if any needs or questions to call ped or go to the ER.

Other Meds: Denies

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386412-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Apr-2010	26-Apr-2010	5	30-Apr-2010	03-May-2010	IN		03-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Fatigue, Headache, Immediate post-injection reaction, Pain in extremity, Tremor

Symptom Text: Pain in arm that wasn't there after injection or anytime before, painful to move arm, tiredness and weakness, headaches, shakiness immediately after vaccine, lingering pain in arm-hurts to touch the place where vaccine was administered.

Other Meds:

Lab Data:

History: Mild asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: 386421-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	30-Apr-2010	30-Apr-2010	0	01-May-2010	03-May-2010	FL		04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Chest pain, Dizziness, Fatigue, Headache

Symptom Text: Fatigue, Weakness, Headache, Dizziness, Chest Pain

Other Meds: Estro-Step FE, Acyclovir

Lab Data: Chest XRay, Bloodwork, EKG, Cardiac Monitor

History: Genital Herpes, No Allergies.

Prex Illness: No.

Prex Vax Illns:

Vaers Id: **386429-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Apr-2010	16-Apr-2010	0	02-May-2010	03-May-2010	IA		04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	08199	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	15584	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope--did not go all the way out.

Other Meds:

Lab Data: none

History: penicillin

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386431-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Apr-2010	28-Apr-2010	0	03-May-2010	03-May-2010	MI		07-May-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1563Y	1	Left arm	Unknown	
TDAP	SANOFI PASTEUR	C3356AA	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0671Y	0	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U3064AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperventilation, Lip oedema, Pruritus, Throat tightness, Urticaria

Symptom Text: 17:00 given shots 5-10 mins after shots started with itching. 17:15 given 1.5 tsp BENADRYL & 1/2 tsp 15 min later. Felt like throat closing. Hives appeared. No wheezing, mild edema of lips, some hyperventilation. 17:45 given 60 mg of SOLUTAB PRELONE & 15 ml MAALOX. 18:00 calmer breathing, hives resolving less itching.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **386449-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	28-Apr-2010	28-Apr-2010	0	03-May-2010	03-May-2010	VA		05-May-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0279X	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045CA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor, Skin warm

Symptom Text: Within 3-5 minutes after receiving a TDAP and HPV vaccine, the patient c/o feeling faint when she stood up. She was immediately assisted to an exam table where she was placed in a horizontal position BP = 102/66. Her skin color was pale and she was diaphoretic. After 15 minutes she was raised to a sitting position BP = 106/72 skin color improved & was warm & dry. After 5 minutes of sitting, she felt much better and was discharged.

Other Meds: DEPO PROVERA 150mg IM given in left deltoid

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **386472-1** **Related reports:** 386472-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Apr-2010	21-Apr-2010	0	03-May-2010	04-May-2010	IL		05-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	11784	0	Left arm	Unknown	
	HEPA	MERCK & CO. INC.	00952	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Enuresis, Loss of consciousness, Pain in extremity, Tonic clonic movements

Symptom Text: Patient received Hepatitis A (1st dose) and HPV (1st dose). C/O arm pain - sat down. Felt dizzy. Passed out then noted to have rhythmic tonic clonic movement of upper arms followed by enuresis. Lasted approximately 1 minute.

Other Meds: None

Lab Data: EEG; Electrolytes; Ca++; Magnesium

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **386472-2** **Related reports:** 386472-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Apr-2010	21-Apr-2010	0	04-May-2010	05-May-2010	IL	WAES1004USA03913	05-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0095Z		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1178Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Electroencephalogram, Laboratory test

Symptom Text: Initial and follow-up information has been received from a registered nurse and a physician concerning a 14 year old female with no pertinent medical history who on 21-APR-2010 was vaccinated IM with a first dose of GARDASIL (lot # 663559/1178Y) and a dose of VAQTA (lot # 667009/0095Z). There were no concomitant medications. It was reported that on 21-APR-2010, five minutes after the vaccination, the patient experienced seizure which lasted about 1 minute. The patient went to the emergency room where lab work was done (results not specified) but she was not admitted. On 26-APR-2010, the patient had an EEG done (results pending). As of this date, the patient had not been referred to neurology or any other specialty, awaiting results of EEG. The patient recovered from seizure, but neither physician nor nurse would say if the event was disabling or life-threatening until further testing was done. Upon internal review, the event of seizure was considered an Other Important Medical Event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **386486-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	19-Apr-2010		03-May-2010	04-May-2010	--	WAES1004USA03400	04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Carcinoma in situ, Papilloma viral infection, Vulval cancer

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female patient who on unknown dates was vaccinated with the three doses GARDASIL (route and lot numbers not provided). It was reported that the patient received GARDASIL series at another physician's office. The patient did not know where she received the vaccinations. On 19-APR-2010 the patient experienced "vulvar carcinoma in situ" after getting all three doses of GARDASIL. The patient's vulvar carcinoma was confirmed upon biopsy. The patient was diagnosed positive for HPV "high risk genotype cervical". The patient was scheduled for a Pap test. The patient was referred to a Cancer Center. The patient's outcome was unknown at the time of reporting. The patient sought unspecified medical attention. Upon internal review, vulvar carcinoma in situ was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: biopsy, positive for HPV "high risk genotype cervical"

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **386487-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Oct-2009	01-Oct-2009	0	03-May-2010	04-May-2010	CA	WAES1004USA03404	04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Blood test, Myalgia, Viral infection, Wheelchair user

Symptom Text: Information has been received from a physician concerning a female patient with a history of obesity who on an unknown date, was vaccinated with a dose of GARDASIL (series, route and lot number unspecified). It was reported that the patient received other vaccines but which ones were unspecified. A week after the vaccination, "sometime in October or November 2009", the patient experienced muscle pain in their arms and legs so the patient went to the emergency room. At the emergency room, the patient had to be put in a wheel chair because of the muscle pain. A serum creatine kinase (CPK) test was performed an the levels were over 1000. A blood work test was performed and the results were not provided. A complete blood cell count (CBC) work up was performed and the results were that probably the patient had a viral infection (unspecified). The physician reported that the patient stopped the series of GARDASIL and had recovered (date not reported). The patient was initially seen by another physician. Viral infection was considered to be disabling by the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Serum creatine kinase, over 1000; complete blood cell, probably viral infection

History: Obesity

Prex Illness:

Prex Vax Illns:

Vaers Id: 386488-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Sep-2008	25-Jul-2009	306	03-May-2010	04-May-2010	FR	WAES1004USA04281	04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0354U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abasia, Areflexia, Asthenia, Blood creatine phosphokinase increased, Dermatitis allergic, Dizziness, Guillain-Barre syndrome, Hyporeflexia, Hypotonia, Immunoglobulin therapy, Mastitis, Muscular weakness, Nerve conduction studies abnormal, Nerve root lesion, Posture abnormal, Quadriparesis

Symptom Text: Information has been received from health authority (PEI2010003696). A general practitioner reported that a 13 year old female patient with a history of deliberate self-harm was vaccinated with a third dose of GARDASIL (lot number 0354U; batch number NF58150) on 22-SEP-2008. On 25-JUL-2009, the patient developed weakness of her leg, then she limped. As from 27-JUL-2009 the symptoms were increasing. On 28-JUL-2009 she was not any longer able to walk and was admitted to hospital. In addition, she experienced weakness of her hands up to the proximal wrists. A few weeks before admission she experienced recurrent dizziness from which she recovered spontaneously. One week before admission to hospital the patient had a left-sided mastitis. After oral treatment with cefuroxime (250 mg/twice a day) until 28-JUL-2009 she recovered from mastitis. Physical investigation revealed an absent patellar reflex, a hardly redeemable Achilles tendon reflex, missing muscle tone and strength in her legs and slightly reduced muscle tone and strength of her hands and arms. She could neither sit or stay. At admission routine laboratory values were within normal limits. During the further course CK increased up to 406. Serology was negative for Borrelia-IgC, mycoplasmas and enteroviruses-PCR. Gangliosid-antibodies had values of GM 1-antibodies IgM 13.1 and GD 1b-antibodies IgM 11.5. CSF was normal, the culture was sterile. CSF serology showed the following results: HSV- (herpes simplex virus) and VZV (varicella zoster virus) antibodies IgM were negative, HSV-DNA and picornavirus-RNA, enteroviruses-PCR negative. Stool sample was negative for rotavirus-antibodies, Helicobacter pylori-antibodies, picornavirus-RNA and enteroviruses-PCR. Shigella, Salmonella, Yersinia and Campylobacter had not been detected. An MRI of spinal column was performed on 29-JUL-2009 and showed normal results. An EMG (electromyogram) and nerve conduction velocity test revealed electroneurographical a generalized leg-emphasised radicular neurogenic lesion with absent F

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 29Jul09, spinal column: normal results; electromyography, 29Jul09, generalised leg-emphasised radicular neurogenic lesion with absent F-answer for all examined nerves; magnetic resonance imaging, 31Jul09, cerebru

History: Immunisation; Deliberate self-harm

Prex Illness:

Prex Vax Illns:

Vaers Id: **386489-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Sep-2008	20-Mar-2009	179	03-May-2010	04-May-2010	FR	WAES1004USA04282	04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1172U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Central nervous system lesion, Demyelination, Disability, Multiple sclerosis, Neurological examination abnormal, Optic neuritis, Pleocytosis, Sensorimotor disorder, Spinal disorder, Visual impairment

Symptom Text: Information has been received from an health authority (reference PEI2009032426). A neurologist reported that a previous healthy 17 year old female patient received a complete vaccination series with three doses of GARDASIL IM on 22-SEP-2008 (first dose, lot number 1172U; batch number NH13130), on 24-NOV-2008 (second dose, lot number 1147U; batch number NH17630) and on 10-MAR-2009 (third dose, lot number 1147U; batch number NH17630). Approximately on 20-MAR-2010, ten days post vaccination, the patient experienced a first exacerbation of sensorimotor disorder of her right arm. The following nuclear spin resonance tomography showed multiple inflammatory cranial lesions with a cerebral focus in the area of cervical spin vertebral body 2/3. CSF showed lymphatic pleocytosis with 18 cells/mcl and oligoclonal bands. That time the patient was treated with a steroid high dose therapy and the immunomodulator COPAXONE. In May 2009 the patient experienced a left-sided optic neuritis and was again treated with a steroid high dose therapy. On 04-JUN-2009 the patient presented again to the outpatient department. The neurological examination showed an expanded disability status score (EDSS) of 1.0 points with a slight visual disturbance. The physician decided to continue immunomodulatory treatment with COPAXONE. On 18-SEP-2009 an MRI check-up of cervical, thoracal spine and cranium was performed. It showed right-sided frontal new demyelinating focuses with signs of activity. The other demyelinating focuses were unchanged since last MRI on 06-APR-2009. Further the MRI check-up of cervical and thoracal spine showed a regression of the multiple sclerosis plaque in the area of cervical spin vertebral body 2/3 since the last MRI on 06-APR-2009 but without being a normal results. Currently no signs of activity. HA coded: multiple sclerosis, sensory disturbance. Sensorimotor disorder, oligoclonal band CSF abnormal, Left-sided optic neuritis and expanded disability status score of 1.0 points with a slight visual disturbance were consid

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, ??Mar?09, nuclear spin resonance topography and see narrative; Magnetic resonance imaging, 06Apr09, See narrative; Magnetic resonance imaging, 18Sep09, check up of cervical, thoracal spine and cranium: see narrat

History: Immunisation; Immunisation;

Prex Illness:

Prex Vax Illns:

Vaers Id: **386491-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Apr-2008	19-Apr-2010	748	03-May-2010	04-May-2010	FR	WAES1004USA04596	04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical conisation

Symptom Text: Information has been received from a gynaecologist on 19-APR-2010. A 19 year-old female underwent a cervical conisation after she had received the 3 doses of GARDASIL (batch number(s) not reported) respectively in October 2007, January 2008 and April 2008. Following conisation, HPV typing was found negative. The outcome was not reported. Upon internal review the cervical conisation and human papilloma virus test negative were considered medically significant. The case was linked with serious WAES No: 1004USA04600. Other business partner numbers include: E2010-02586. Additional information has been requested.

Other Meds: None

Lab Data: Pap test, 19?Apr08, negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **386556-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	M	29-Apr-2010	29-Apr-2010	0	03-May-2010	04-May-2010	OK		04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Pruritus generalised

Symptom Text: Red, soreness, swelling at site of injection. Whole body itching.

Other Meds: Wellbutrin sr - 150mg bid Trileptal - 150mg bid Optivar - one drop bid

Lab Data:

History: Doxycycline

Prex Illness: n/a

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386557-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	M	28-Apr-2010	29-Apr-2010	1	03-May-2010	04-May-2010	TX		04-May-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0995Y		Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037A		Left arm	Intramuscular	
MEN	SANOFI PASTEUR	U3021AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0075Y	0	Right arm	Intramuscular	
HEPA	MERCK & CO. INC.	1257Y	0	Left arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB818AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pain in extremity, Skin warm

Symptom Text: PT WOKE UP WITH LA RED, SWOLLEN, AND PAINFUL. SITE MEASURED ABOUT 40MM IN LENGTH AND WAS HOT TO TOUCH.

Other Meds:

Lab Data:

History:

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386581-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		04-May-2010	05-May-2010	--	WAES1004USA03600	05-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female patient of unknown age who on an unspecified date was vaccinated with an unknown dose of GARDASIL. The patient's medical history, past drug history and concomitant medications were unknown. On an unknown date the patient experienced seizures. It was unknown if any laboratory testing was performed. As of 21-APR-2010, the patient was no longer receiving GARDASIL and it was unknown if the seizures continued. It was unspecified if the patient sought medical attention. Upon internal review, seizures was considered serious as an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386582-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Apr-2010	10-Apr-2010	1	04-May-2010	05-May-2010	FR	WAES1004USA03753	05-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NG31230	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Nausea, Sensory disturbance, Tremor

Symptom Text: Information has been received from a pediatrician concerning a 12-year old female with no pertinent medical history reported who on 09-APR-2010 was vaccinated intramuscularly into the deltoid muscle with first dose of GARDASIL (lot number NG31230, batch number NJ08230). One day post vaccination, on 10-APR-2010, the patient developed nausea, headache and trembling. Then on 14-APR-2010 she additionally experienced dizziness and sensory disturbances in her legs. A neurological investigation and a taken blood count on 15-APR-2010 showed no pathological findings. On 22-APR-2010, the patient was admitted to the hospital due to ongoing symptoms. At the time of reporting, the patient had not recovered. Other business partner numbers included: E2010-02603. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 15Apr10, Neurological investigation: no pathological findings; complete blood cell count, 15Apr10, No pathological findings

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **386583-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-May-2009	20-May-2009	16	04-May-2010	05-May-2010	FR	WAES1004USA03808	02-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Dysaesthesia, Muscle tightness, Pain, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a health authority (HA) (reference number TO20091418) concerning a 16 year old female patient who on 04-MAY-2009 was vaccinated with a second dose of GARDASIL. Subsequently the patient developed paraesthesia in the upper limbs. She had received the first dose of GARDASIL on 07-MAR-2009. The patient was a tobacco user and had personal history of psychological difficulties following a death and after the separation of her parents. She also had an 11-kg weight loss further to dietary restrictions. The patient had long-term hormonal contraception. On 20-MAY-2009, the patient developed pains in the left elbow, subsequently extending to the forearm, then to the hand. Symptoms subsequently became bilateral. Pains were characterized by stretching, tightness and paraesthesia, with an onset time rather in the mornings and evenings. The physician suggested and adverse effect of GARDASIL to explain the cause of such paraesthesia. The Health Authority (HA) stated that paraesthesia appeared shortly after the second injection of GARDASIL. -Biological work-up: not available. -Non-drug induced aetiologies ruled out: clinical examination found no sign of sensorymotor deficit. There was no pyramidal syndrome, no issue with cranial nerves and no Lhermitte's sign. MRI of the cervical bone marrow was normal and no vitamin B12 deficiency was found. -Evolution: symptomatic treatment with low doses of RIVOTRIL in drops was implemented on 09-SEP-2009. However, as of 14-OCT-2009, dysaesthetic sensations of the upper limbs persisted. As of 17-NOV-2009, symptoms persisted but had slightly regressed. Practice of sports, ie handball, was still impossible for the patient. The health authorities assessed the causal relationship between the reported reaction and vaccination as doubtful (C2 S1 I1) according to the Foreign method of assessment. The seriousness criterion reported by the HA was "other medically important condition" (not specified). The HA coded the event of "paraesthesia upper limb". Other business

Other Meds: Unknown

Lab Data: magnetic resonance imaging, Of the cervical bone marrow was normal and no vitamin B12 deficiency was found

History:

Prex Illness: Tobacco user; Psychological disorder NOS; Contraception; Weight decreased

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386585-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		04-May-2010	05-May-2010	FR	WAES1004USA04600	05-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical conisation, Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a gynecologist concerning a now 19 year old female patient who developed cervical intraepithelial neoplasia III after she had received the three doses of GARDASIL (batch number not reported) when she was 16 years old. Oncogenic HPV was identified. The patient had a conisation. The outcome was not reported. Case linked with serious report No E2010-02586 (WAES# 1004USA04596) (same reporter, same product). Upon internal review the events were considered medically significant. Other business partner numbers include: E2010-02528. No further information is available.

Other Meds: Unknown

Lab Data: Cervix HPV DNA assay, Positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386590-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Apr-2007	12-Aug-2007	129	04-May-2010	05-May-2010	AR		29-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0171U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Anxiety, Back pain, Chest pain, Confusional state, Contusion, Ear pain, Fatigue, Gastrointestinal disorder, Gastrooesophageal reflux disease, Headache, Insomnia, Intestinal functional disorder, Lymphadenopathy, Migraine, Myalgia, Nausea, Neck pain, Pelvic pain, Pericarditis, Photophobia, Pleural effusion, Pyrexia, Rash, Swelling, Thrombosis, Vomiting, Weight decreased

Symptom Text: Pleural effusion, stomach/pelvic pain - ER visit - no treatment. Nausea, headaches, weight loss, anxiety, pericarditis, light sensitivity, sore muscles, back pain, no recovery, swollen lymph nodes, acid reflux - no treatment. Chest pain, confusion, rashes, fatique, fevers, migrains, bruises, neck pain, and vomiting. 7/23/10 swelling, insomnia, blood clots, and intestinal problems and earaches.

Other Meds: None

Lab Data: Colonoscopy, endoscopy, laproscopy, blood work up - normal results

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386599-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	19-Apr-2010	19-Apr-2010	0	04-May-2010	04-May-2010	CA		25-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	13774	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypoaesthesia, Injection site pain, Muscle spasms, Nausea, Neck pain, Pyrexia

Symptom Text: Pt states pain at injection site and radiating up her neck x 5 days, muscles spasms, numbness, fever, dizzy, nausea. Refused referral to urgent care and primary care provider.

Other Meds: None

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386619-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Apr-2010	07-Apr-2010	0	04-May-2010	04-May-2010	CO		04-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3355AA	5	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1312X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Dyskinesia, Fall, Head injury, Loss of consciousness, Musculoskeletal stiffness, Syncope

Symptom Text: Fainted, fell to ground, hit her head on floor or table (unsure which). Stiffening and jerking movements. Unconscious approx. 30 seconds.

Other Meds:

Lab Data: Head CT.

History: hx. of fainting

Prex Illness: none known

Prex Vax Illns:

Vaers Id: 386685-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jul-2009	25-Aug-2009	32	05-May-2010	06-May-2010	FR	WAES1004USA04283	02-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Guillain-Barre syndrome, Haemangioma, Inflammation, Intervertebral disc disorder, Muscular weakness, Nerve conduction studies abnormal, Nerve root lesion, Nuclear magnetic resonance imaging spinal cord abnormal

Symptom Text: Information has been received from a foreign health authority (PEI2009030910). On 24-JUL-2009, a 15 year old female patient was vaccinated with a third dose of GARDASIL. On 25-AUG-2009 during hospitalization in AUG-2009 (no report was provided) the diagnoses of Guillain-Barre syndrome with polyradiculitis were established due to weakness of her lower extremities (onset not reported). A nuclear spin resonance tomography of the spinal canal (exact date not reported, in the time frame of the hospitalisation) had been performed for clarifying the diagnosis and had shown pathological findings in the area of the vertebral bodies which partially had been interpreted as Schmorl's nodes or as haemangioma. Under treatment with physiotherapy the symptoms improved and she had no more restriction in her daily life. On 27-OCT-2009, the patient presented to a neuro-pediatrician for follow-up investigations. The clinical examination showed no abnormal findings. The check-up of the motoric nerve conduction velocity of the peroneus nerve showed in comparison to the prior examination changes but still prolonged distal latencies and borderline amplitudes. Nevertheless the physician stated that the girl recovered completely from Guillain-Barre syndrome and polyradiculitis. A nuclear spin resonance tomography check-up of the spinal (date not reported) canal showed again the unchanged unclear pathological findings which were already interpreted as Schmorl's nodes or also as inflammatory changes. The outcome for these lesions was unknown. The final outcome was not reported. Previous doses of GARDASIL were given on 16-FEB-2009 and on 02-APR-2009, toleration was not reported. HA (PEI) coded: Guillain-Barre syndrome, polyradiculitis, Schmorl's nodes. Guillain-Barre syndrome, polyradiculitis, Schmorl's nodes, haemangioma and inflammatory reaction were considered to be other important medical events. The case was closed. Other business partner included: E2010-02697. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **386686-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Apr-2009	01-Apr-2009	0	05-May-2010	06-May-2010	FL	WAES0905USA01843	06-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Pregnancy test, Ultrasound scan

Symptom Text: Information has been received from a Registered Nurse (R.N.) concerning an 18 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who on an unspecified date was vaccinated with a dose of GARDASIL (Lot # not reported). There was no concomitant medication reported. It was reported that the patient was vaccinated with GARDASIL during pregnancy. The patient was seen at the practice. On an unspecified date a home pregnancy test and an ultrasound were performed (results not provided). The date of the last menstrual period was on 25-MAR-2009 and the estimated delivery date was 30-DEC-2009. Follow up information was received from a health professional. It was reported that they saw this patient only twice. The first time was in May 2009 and then on 08-JUN-2009 in the emergency room (ER). The patient was seen in the ER due to miscarriage. They have not seen the patients since that time. The reporter mentioned that the patient did not receive the HPV in their office. The patient had reported receiving it in April 2009. Upon internal review, miscarriage was considered to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 3/25/2009)

Prex Vax Illns:

Vaers Id: 386689-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Oct-2009	13-Oct-2009	7	05-May-2010	06-May-2010	FR	WAES1004USA04601	06-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Lymphocyte count abnormal, Malaise, Myalgia, Pyrexia

Symptom Text: Initial information has been received on 19-APR-2010 from the patient's mother concerning her daughter, a 15 year old female (14 years old at the time of event), who on 06-OCT-2009 received the first dose of GARDASIL (Batch # not reported) 0.5 mL, route and site not reported. It was reported that since 13-OCT-2009 the patient began to feel unwell. The doctor diagnosed it as a possible catarrh. As of 02-NOV-2009 she began with high fever, she had to be taken to the emergency room on 3 occasions. According to the test that were performed on the patient, C-reactive protein levels were very high, and lymphocytes were altered (values not reported, date not reported). On 17-NOV-2009 the patient was hospitalized due to a high fever peak, she remained hospitalized for 10 days. Further test showed a very high erythrocyte sedimentation rate, other parameters were also altered (date not reported, values not reported). The patient had headaches, muscle pain and malaise. The patient was not recovered. Relevant Test/Laboratory data: Test performed on an unspecified date: C-reactive protein levels were very high, and lymphocytes were altered (values not reported). Very high erythrocyte sedimentation rate, other parameters were also altered (values not reported). Other Business Partners numbers include E2010-02533. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, Other parameters were also altered (values not reported); WBC count, were altered (values not reported); serum C-reactive protein, levels were very high; erythrocyte sedimentation rate, very high erythrocyte sedi

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386714-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Nov-2009	20-Mar-2010	110	05-May-2010	05-May-2010	GA		06-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscular weakness, Nausea, Palpitations

Symptom Text: Completely healthy teenager developed muscle weakness, severe nausea and heart palpitations after about 5-6 weeks of receiving second shot. Symptoms lasted for about 4 weeks and mild persistent nausea and some muscle weakness for about 8 weeks. Called night nurse and went to physician.

Other Meds: NONE.

Lab Data: Blood test were fine but no explanation for symptoms. Unavailable diagnostic test for vaccine.

History: None

Prex Illness: None

Prex Vax Illns: NONE~ ()~~0.00~Patient

Vaers Id: **386770-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		06-May-2010	07-May-2010	MD	WAES1004USA04677	07-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who, on an unspecified date, was vaccinated with a dose of GARDASIL (dose and lot number not reported). Concomitant therapy included meningococcal vaccine (unspecified). The nurse reported that "the patient was administered a dose of the vaccine, which dose was unspecified". It was reported that right after receiving the vaccination "about a month ago" the patient was lying down in the office and when she went to get a glass of water she passed out. The patient was also showing "seizure-like" activity". The patient sought for unspecified medical attention. Upon internal review, seizure-like activity was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **386771-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-May-2009	20-May-2009	16	06-May-2010	07-May-2010	FR	WAES1004USA04738	03-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Dysaesthesia, Muscle tightness, Pain in extremity, Paraesthesia, Weight decreased

Symptom Text: Information has been received from a Health Authority (reference number TO20091418) concerning a 16 year old female who on 04-May-2009 was vaccinated IM with second dose of GARDASIL (lot number and batch number not reported). IT was noted that the patient developed paresthesia in the upper limbs after she received this dose. The patient had received the first dose of GARDASIL (dose, route and lot number not reported) on 07-Mar-2009. The patient was a tobacco user and has a personal history of psychological difficulties following a death and after the separation of her parents. She also had an 11 KG weight loss further to dietary restriction. The patient had long-term hormonal contraception. On 20-MAY-2009, the patient developed pains in the left elbow, subsequently extending to the forearm, then to the hand. Symptoms subsequently became bilateral. Pains were characterized by stretching, tightness and paresthesia with an onset time rather in the mornings and evenings. Biological work up was not available. No drug-induced etiologies ruled out. Clinical examination found no sign of sensory-motor deficit. There was no pyramidal syndrome, no issue with cranial nerves and no Lhermitte's sign. MIR of cervical bone marrow was normal and no vitamin B12 deficiency was found. Symptomatic treatment with low doses of RIVOTRIL in drops was implemented on 09-SEP-2009. However, as of 14-OCT-2009, dysaesthetic sensations of the upper limbs persisted. As of 17-NOV-2009, symptoms persisted but had slightly regressed. The practice of sports, i. e. handball, was still impossible for the patient. The physician suggested an adverse event of GARDASIL to explain the cause of such paraesthesia. Paraesthesia appeared shortly after the second dose of GARDASIL. The agnecy assessed the causal relationship between the reported reaction and vaccination as "doubtful" (C2 S1 I1) according the local method of assessment. The seriousness criterion reported by the agency was "other important medical condition" (not specified). The agency coded the e

Other Meds: Unknown

Lab Data: magnetic resonance imaging, cervical bone marrow: normal

History:

Prex Illness: Tobacco user; Psychological disorder NOS; Weight decreased; Contraception

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386773-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Feb-2009	01-Feb-2009	0	06-May-2010	07-May-2010	FR	WAES1004USA04742	26-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Brain scan normal, Encephalitis, Incorrect route of drug administration

Symptom Text: Information has been received from a health authority (CN20100207 and CN0900047) concerning a 20 year old female who on 01-FEB-2009 was vaccinated with GARDASIL subcutaneous (batch number not reported). This case was identified as a misuse by the company (incorrect route of administration), although not reported as such by the HA: the recommended route for GARDASIL is the intramuscular one. The patient had no relevant personal medical history. A few days after vaccination, the patient experienced an encephalitic reaction and was hospitalised. CT angiography, brain CT scan and MRI scan were normal. The patient recovered on 12-FEB-2009. The Health Authorities assessed the causal relationship between the reported reaction and vaccination as "doubtful" (C1 S1 I1) according to the foreign method of assessment. The seriousness criterion reported by the HA was hospitalisation. The HA coded the event encephalitic reaction. No further information is available. Other business partner included E2010-02626.

Other Meds: Unknown

Lab Data: computed axial tomography, Angiogram, normal; head computed axial tomography, normal; magnetic resonance imaging, normal

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386774-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	06-May-2009	05-Jun-2009	30	06-May-2010	07-May-2010	FR	WAES1004USA04745	07-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Demyelination, Hypoaesthesia, Lhermittes sign, Muscular weakness

Symptom Text: Information has been received from a Health Authority under the reference GR-EOF-91687 and transmitted through a distributor, Vianex, under the reference: SPV10019. A 21 year old female patient with a family history of multiple sclerosis, had received a second single dose of GARDASIL, 0.5 mL, (batch # and site of administration not reported), via intramuscular route on 06-MAY-2009. Thirty days after the second dose, the patient presented numbness in her right hand fingers. She also presented right arm weakness. Subsequently, the feeling of numbness spread to the left side of her body. The patient also presented Lhermitte sign. Brain MRI revealed multiple demyelination foci. Cervical MRI revealed demyelination foci in A2. CSF electrophoresis showed oligoclonal IgG. The patient had not recovered at the time of the report. The patient had received a first dose of GARDASIL (batch # and site of administration not reported) via intramuscular route on 06-APR-2009. No concomitant medication was reported. Relevant test/Laboratory data: MRI revealed multiple demyelination foci and CSF electrophoresis showed oligoclonal IgG. Other business partners included: E2010-02838. Additional information has been requested.

Other Meds: None

Lab Data: magnetic resonance imaging, revealed multiple demyelination foci; diagnostic laboratory test, Cerebrospinal fluid electrophoresis showed oligonal IgG.

History:

Prex Illness: Familial risk factor

Prex Vax Illns:

Vaers Id: **386776-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Apr-2010	29-Apr-2010	0	06-May-2010	07-May-2010	OH	WAES1005USA00021	07-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with no drug reactions or allergies who on 29-APR-2010 was vaccinated intramuscularly with a first dose of GARDASIL. On 29-APR-2010 the patient developed itching all over her body after receiving her first dose and only dose of GARDASIL. The patient sought unspecified medical attention and was given BENADRYL via intramuscular injection. No laboratory diagnostic studies were performed. On 29-APR-2010, the patient had fully recovered from this event. "The patient was given BENADRYL via intramuscular injection" was considered to be an other important medical event by the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386782-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Apr-2010	06-Apr-2010	0	06-May-2010	07-May-2010	FL	WAES1004USA04528	07-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, No reaction on previous exposure to drug

Symptom Text: Information has been received from a medical assistant concerning a 13 year old female with a history of attention deficit non-hyperactivity disorder and no drug allergies, who on 09-SEP-2009 was vaccinated with the first dose of GARDASIL (lot # 659054/0315Y, IM, 0.5ml), on 11-NOV-2009 with the second dose (lot # 663453/0249Y, IM, 0.5ml) and the third dose on 06-APR-2010 (lot # 659054/0315Y, IM, 0.5ml). Concomitant therapy included METADATE CD. On 06-APR-2010 the patient experienced a seizure less than 5 minutes after her third dose. The patient immediately regained consciousness with smelling salts. She was confused for less than 30 seconds. There were no labs or diagnostic tests performed. The patient received unspecified medical attention. On 06-APR-2010, the patient recovered. Follow up information has been received from the medical assistant indicating that the patient had no previous history of seizures and no problems after the first and second doses of GARDASIL. No other vaccine was given on 06-APR-2010. No treatment was required and no referrals were made. Upon internal review, the events were considered to be other important medical events. No further information is available.

Other Meds: METADATE

Lab Data: None

History: Attention deficit disorder of childhood without mention of hyperactivity

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386877-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-May-2010	05-May-2010	1	06-May-2010	07-May-2010	NY		11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y		Left arm	Intramuscular	
	IPV	SANOFI PASTEUR	B0476		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3046AA		Left arm	Intramuscular	
	MMR	MERCK & CO. INC.	0563Y		Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site oedema, Pyrexia

Symptom Text: Erythema and edema at injection site 8 hours after administration. Fever of 103 degrees F. Hydrocortisone 1% cream bid prn.

Other Meds: None

Lab Data:

History: Autism (mild)

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386911-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Apr-2010	28-Apr-2010	0	07-May-2010	07-May-2010	VA		18-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B046AA		Right arm	Intramuscular	
	MMR	MERCK & CO. INC.	1118Y		Left arm	Subcutaneously	
	IPV	SANOFI PASTEUR	D0304		Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1318Y		Right arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB736AB		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Clonus, Dizziness, Feeling abnormal, Vomiting

Symptom Text: Aft immediately upon completion of administrating vaccines pt stated 'what a bad feeling I have' and was observed by this nurse to have a fainting spell with clonic movements. Regained alertness within 30 seconds. Pt was seated in chair at time of occurrence. Legs were elevated. Juice given. Pt also vomited small amount. Pt was assessed by nurse practitioner. Respirations normal. Pt was monitored.

Other Meds: PPD, C3368AB, ID, L arm

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: None~ ()~~0.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386933-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	23-Sep-2008	16-Jun-2009	266	07-May-2010	10-May-2010	--	WAES0810USA04931B1	15-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Congenital anomaly, Drug exposure during pregnancy

Symptom Text: Information has been received from a health care professional who reported on 16-JUN-2009 normal baby was born with congenital anomaly. The mother of the baby was vaccinated with a first dose of GARDASIL (lot # not reported) on 23-SEP-2009. Also the mother's baby received concomitant therapy MOTRIN and promethazine. At the time of this report, the baby's outcome was unknown. The mother adverse event was capture WAES# 0810USA04931. Additional information has been requested.

Other Meds: MOTRIN; promethazine

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386936-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-Mar-2009	20-Mar-2009	0	07-May-2010	10-May-2010	--	WAES0904USA00017	11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse, for the Pregnancy Registry for GARDASIL, concerning a 22 year old female with no pertinent medical history, allergies or drug reactions who on 20-MAR-2009 was vaccinated with GARDASIL (lot no., dose and route not reported). The nurse reported that the patient was pregnant when the vaccine was administered. A pregnancy test was performed at the doctor's office that was positive. The patient's LMP was on 20-FEB-2009 and the EDD: 27-NOV-2009. Follow up information has been received from the licensed practical nurse regarding the patient. The nurse stated that the patient's last menstrual period was actually 15-FEB-2009 (previously reported as 20-FEB-2009). On 27-JUL-2009, patient experienced miscarriage at gestational age of 23 weeks. It was asked if there were any previous studies were done following the miscarriage to determine a reason but the nurse said no and mentioned that this was not the patient's first miscarriage. Miscarriage was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 2/15/2009)

Prex Vax Illns:

Vaers Id: **386940-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	15-Mar-2009	20-May-2009	66	07-May-2010	10-May-2010	FR	WAES1004USA04744	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Demyelination, Diplopia, Optic neuritis

Symptom Text: Information has been received from a health authority (Reference GR-EOF-91688) and transmitted through a distributor, VIANEX (Reference SPV10020) concerning a 28 year old female patient who received a single dose of GARDASIL (0.5 ml batch number and site of administration not reported) via intramuscular route on 15-MAR-2009. The patient presented diplopia and retrobulbar pain on 20-MAY-2009. Brain magnetic resonance imaging (MRI) revealed multiple demyelination foci, cerebrospinal fluid (CSF) electrophoresis showed oligoclonal bands and evoked potentials revealed right N-P37 prolongation. The patient recovered with sequelae on 10-JUN-2009. The patient had medical history of "cervical information' and cervical fibrous tissue resection. No concomitant medication was reported. Other business partner numbers include: E2010-02840. Additional information has been requested.

Other Meds: None

Lab Data: magnetic resonance imaging, Brain MRI revealed multiple demyelination foci; visual evoked potential, Right N-P37 prolongation; CSF protein electrophoresis, Oligoclonal bands

History: Cervical lesion excision; Cervix disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: **386942-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Dec-2009	21-Dec-2009	7	07-May-2010	10-May-2010	FR	WAES1004USA04750	11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a health authority (HA) (NO-NOMAADVRE-FHI-2010-10406, FHI, 10-1043) concerning a 12 year old female patient who was vaccinated with the first dose of GARDASIL (Batch number not reported, parenteral route) on 22-SEP-2009 and second dose of GARDASIL (Batch number not reported, parenteral route) on 14-DEC-2009. Concomitant therapy included CIRCADIN, CONCERTA, loratadine and RITALIN. HA coded convulsions generalized (causality possible) with onset one week post vaccination in December 2009 (approximately on 21-Dec-2009). Same reaction followed vaccination with dose one (no onset date provided). The patient had continuing attention deficit/hyperactivity disorder (ADHD) and sleep disturbance. The outcome was recovered. Convulsions generalised was considered to be an other important medical event by the reporter. Other business partner numbers include: E2010-02793. Case is closed. No further information is available.

Other Meds: CIRCADIN; CONCERTA; RITALIN; loratadine

Lab Data: Unknown

History:

Prex Illness: Attention deficit/hyperactivity disorder; Sleep disturbance

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386944-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	23-Mar-2010	23-Mar-2010	0	07-May-2010	10-May-2010	FR	WAES1005USA00196	11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Muscle contractions involuntary, Mydriasis, Pallor, Reaction to previous exposure to any vaccine

Symptom Text: Information has been received from a physician concerning an approximately 24 year old female patient with no allergy in anamnesis who on 23-MAR-2010 was vaccinated with a dose of GARDASIL. On 23-MAR-2010, immediately after the administration, the patient became pale, her pupils expanded and she had fasciculation in her face. This lasted one minute. After one minute the symptoms disappeared, the patient was not hospitalized and she was able to go home. After this reaction occurred, the patient remembered that she had similar reaction after hepatitis vaccination (unspecified). At the time of the report, the patient recovered. Pallor, pupils expanded and fasciculation were considered to be other important medical events by the reporter. The causal relationship between pallor, pupils expanded and fasciculation and therapy with GARDASIL was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Allergy to vaccine

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386945-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	01-Aug-2009		07-May-2010	10-May-2010	--	WAES1005USA00236	30-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Areflexia, Arthralgia, Asthenia, Back pain, Blindness transient, Conversion disorder, Convulsion, Crying, Diarrhoea, Dyskinesia, Electroencephalogram normal, Endotracheal intubation, Extubation, Fatigue, Gait disturbance, Gaze palsy, Headache, Hemiparesis, Hypertension, Hypoaesthesia, Hypokinesia, Intensive care, Lymphadenopathy, Mental status changes, Migraine, Nuclear magnetic resonance imaging brain normal, Oropharyngeal pain, Pain, Status epilepticus, Swelling, Unresponsive to stimuli, Vision blurred

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter who on unspecified dates was vaccinated with 3 doses of GARDASIL (lot number not reported). Concomitant therapy included TOPAMAX (ineffective). After completed the dosing schedule for GARDASIL, in August 2009 the patient experienced severe stomach pain, aches, exhaustion, headaches, blurred vision, back pain, swollen glands, sore throat, fatigue, seizures, high blood pressure and very frequent diarrhea. Around " the end of February 2010", on approximately 28-FEB-2010 the patient was hospitalized because" her right arm and leg went numb and she temporary lost vision". Both events were reported as not being related to seizures. On 05-APR-2010 the patient was air lifted from the hospital to another hospital for seizures. On 10-APR-2010 the patient was sent back to the hospital via an ambulance for seizures again. At the time of the report, the patient had not recovered. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 5/13/10 ED, Hospital records and discharge summaries received for dates of service 2/6/10 to 4/11/10. Dx: Migraines, Generalized HA's with R sided weakness, Prolonged altered mental status, status epilepticus, Pseudoseizures. Presented to ED with a worsening migraine HA rated 9.5/10 that was triggered by playing outside. Had been taking Amitryptyline for prophylaxis of migraines, but stopped one week earlier. Associated sx. included blurry vision and numbness in the right upper and lower extremities. Mother gave pt. Advil with little improvement. Pt. medicated for pain control and admitted for observation, discharged the following day. Two months later, presented with altered mental status and seizures. In the ED pt. was nonverbal, with weak responses to commands to squeeze hands. Began seizing when EKG attempted. No cough or gag reflex, unresponsive. Intubated. BP elevated to 160/100's. Transferred to higher level of care a

Other Meds: TOPAMAX

Lab Data: Unknown. The following information was obtained through follow-up and/or provided by the government. 5/13/10 ED, Hospital records and discharge summaries received for dates of service 2/6/10 to 4/11/10. Labs and diagnostics: EEG-Nl, MRI br

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **386947-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Mar-2010	01-Apr-2010	2	07-May-2010	10-May-2010	FR	WAES1005USA00062	11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1334X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Auricular swelling, Bedridden, Burning sensation, Erythema, Gait disturbance, Henoch-Schonlein purpura, Hypersensitivity, Inflammation, Neutrophil count normal, Oedema peripheral, Pain in extremity, Red blood cell count normal, Viral infection

Symptom Text: This case was initially reported by the mother of the patient on 09-APR-2010. Additional information was received from a healthcare professional on 12-APR-2010. A 16 year old female was vaccinated with the first dose of GARDASIL (batch #NL30760, lot # 1334X, site and route not reported) in the left arm on 30-MAR-2010. 2 days post vaccination, on 01-APR-2010 the patient experienced swelling of the left ear, something that lasted for 3 days. She was all red in the ear (onset not reported) and therefore visited the doctor on 06-APR-2010. The doctor suspected ear inflammation and prescribed KAVEPENIN (Meda), cortisone nose spray (manufacturer unknown) and ear drops (manufacturer unknown). Some time after the visit to the doctor, the girl developed swelling of feet and fingers (one finger on each hand was affected), redness and pain of both feet and a burning sensitivity in the feet. The patient revisited the doctor on 08-APR-2010 due to the symptoms of hands and feet and the doctor concluded that the girl was not suffering from an ear inflammation, but most likely experiencing some kind of allergic reaction. The doctor said it could be had been the ear drops (later ruled out) or perhaps vaccination with GARDASIL that had caused the symptoms. 10 microgram CETIRIZIN (Sandoz) was prescribed and she was told to stop the treatment with penicillin, nose spray and ear drops (prescribed on 06-APR-2010). On 09-APR-2010, the girl was feeling better and could now walk without difficulties. According to her mother, she was improving as the day progressed. Test performed on 08-APR-2010: CRP 13, urine sample was OK except for erythrocytes 80 and albumin 0.3, blood tests (for instance erythrocytes and neutrophils) were all normal, Hemoglobin 125g/l and thrombocytes 301. According to the medical record from 08-APR-2010 allergic purpura was diagnosed and the doctor had added "reaction due to virus". However, the doctor did also judge it possible that the cause of the adverse events was GARDASIL. During the winter season 2009/2010 the

Other Meds: Unknown

Lab Data: hemoglobin, 08Apr10, 125 g/l; platelet count, 08Apr10, 301; serum C-reactive protein, 08Apr10, 13; urine RBC count, 08Apr10, 80; urine albumin, 08Apr10, 0.3

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386962-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Apr-2010	23-Apr-2010	0	07-May-2010	07-May-2010	CO		11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: After being given vaccine pt had syncopal episode hitting face/head on wall/floor.

Other Meds: DEPO-PROVERA

Lab Data: X-ray facial bones NL; CT Scan head NS

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **386968-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	06-May-2010	07-May-2010	1	07-May-2010	07-May-2010	TX		11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U3351AA		Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP077AA	0	Right arm	Intramuscular	
	PPV	MERCK & CO. INC.	1190Y	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC5AB037AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0672U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Throat irritation

Symptom Text: Pts mother called 5-7-10 stating that pt had swelling in (R) arm and under (R) armpit and throat irritation.

Other Meds: VERAMYST; XOPENEX; CLARITIN; BENADRYL

Lab Data:

History: Seas allergies

Prex Illness: Sore throat

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386976-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-May-2010	05-May-2010	1	07-May-2010	07-May-2010	CO		10-May-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B046DA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3016AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0914Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Swelling

Symptom Text: Localized swelling and redness 3 cm on 5/5/10, baseball sized area by afternoon of 5/6/10. No fever, pain or other sx.

Other Meds:

Lab Data: none

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **386993-1** **Related reports:** 386993-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Feb-2008	19-Feb-2008	6	07-May-2010	07-May-2010	MD		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Alopecia, Alopecia effluvium, Arthropod bite, Bacterial infection, Body temperature increased, Conjunctivitis, Depression, Dizziness, Fatigue, Feeling hot, Hormone level abnormal, Immune system disorder, Infectious mononucleosis, Kyphosis, Malaise, Neck pain, Pharyngitis, Pharyngitis streptococcal, Rash, Sinusitis, Skin papilloma, Stress, Upper respiratory tract infection, Viral infection, Visual impairment, Vomiting

Symptom Text: Severe abdominal pain, rash, hair loss, black spots before eyes, body temperature being too hot, constant illness, weak immune system, vomiting, dizziness, fatigue, depression. The following information was obtained through follow-up and/or provided by the government. 5/17/10 Outpatient records and correspondence received for dates of service 5/7/08 to 4/28/10. Dx: Multiple warts, Probable insect bite on neck, URI, Pharyngitis, Sinusitis, conjunctivitis, Hormonal imbalance possibly 2/2 BCP's, Hair loss 2/2 stress, hypercholesterolemia, mononucleosis, Strep throat, telogen effluvium, resolving, chronic cervicalgia, cervical kyphosis. Presents with c/o severe abdominal pain; sharp stabbing pains, rash that comes and goes, hair loss; hair that continues to thin dramatically, black spots before eyes, being hot; not being able to regulate body temperature, constant illness; sick with viral or bacterial infections since vaccinations, vomiting; waking in the middle of the night to vomit, dizziness.

Other Meds:

Lab Data: tons of bloodwork and doctors visits. The following information was obtained through follow-up and/or provided by the government. 5/17/10 Outpatient records and correspondence received for dates of service 5/7/08 to 4/28/10. Labs and diagn

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **386998-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	05-May-2010	06-May-2010	1	07-May-2010	10-May-2010	SC		11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1498Y	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy, Hypoaesthesia facial, Injection site pain

Symptom Text: Bells palsy to right of face and numbness to left side of face. Pain at injection site.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387045-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-May-2010	06-May-2010	1	10-May-2010	10-May-2010	FL		26-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1317Y	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	42928AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3246BA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site swelling, Pyrexia

Symptom Text: Injection MENACTRA given on 5/5/10. Lot# 42928AA Exp 5/14/10 site swollen with fever.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387058-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Apr-2008	26-May-2008	35	10-May-2010	11-May-2010	FR	WAES1005USA00230	11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse from the County Health Unit concerning a 14 year old female who on 21-APR-2008 was vaccinated with a third dose of GARDASIL at school. On 26-MAY-2008, 35 days after the patient received her third dose, she began suffering from seizures and has continued since then. When the patient first started having seizures she was admitted to the epilepsy unit of a hospital for 1 week. Her EEG (electroencephalography) was normal then as well as her MRI (magnetic resonance imaging). It was reported that the patient has continued to have seizures, she could sometimes have clusters of them that could last up to 40 minutes. The seizures sometimes occurred daily and other times she only had them 2 or 3 times a week. Causal relationship between GARDASIL and seizures was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: electroencephalography, ??May?08, normal; Magnetic resonance imaging, ??May?08, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **387072-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-May-2010	07-May-2010	0	10-May-2010	10-May-2010	NY		03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0981Y	2	Right arm	Intramuscular	HPV4
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB417AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Documentation of second Gardasil shot was not done correctly. Gave pt her third (believing it was her second) 3 months too early and less than 1 month from her actual second shot.

Other Meds:

Lab Data:

History: no

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387079-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-May-2010	07-May-2010	1	10-May-2010	10-May-2010	MI		11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Right arm numbness and tingling for several hours. Persisted in hand for 2-3 days.

Other Meds: DMPA 150 mg. Im left arm. given same day

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387110-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Apr-2010	15-Apr-2010	6	10-May-2010	11-May-2010	MI		25-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3351AA		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	03101AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1317Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Bell's Palsy.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387152-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Apr-2009	10-Apr-2009	0	11-May-2010	12-May-2010	ID	WAES0905USA02036	12-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal labour, Breech presentation, Caesarean section, Drug exposure during pregnancy, Prolonged labour

Symptom Text: Information has been received from a female, for the Pregnancy Registry for GARDASIL, concerning her 16 year old daughter with no pertinent medical history or drug reactions/allergies who on 10-APR-2009 was vaccinated with one dose of GARDASIL. The patient became pregnant. The urine pregnancy test was performed in the office. The patient's last menstrual period was 25-MAR-2009, her estimated delivery date was 30-DEC-2009. It was reported that her pregnancy was normal to date. Additional information was received from a health professional concerning that a 16-year-old female patient with no per-existing allergies, birth defects or medical conditions was vaccinated IM in the deltoid region of the right arm with the first dose of GARDASIL vaccine (Lot # 661046/0546X) at 16:00 PM on 10-SEP-2009. The patient was unaware of pregnant at the time of injection. There were no adverse events reported. The patient had no illness at time of vaccination. The patient had no other concomitant medications. Follow-up information has been received from a physician indicated that the patient with no significant past medical history and no family history or smoking history with no obesity and with no previous pregnancies, no pre-term deliveries, no spontaneous abortions, no elective terminations, no stillbirths and on full term delivery who was vaccinated with the first dose of GARDASIL on 10-APR-2009. Concomitant medication included prenatal vitamins from June 2009 to December 2009 daily for pregnancy. The prenatal testing included: On 23-JUN-2009 at 13 weeks and on 18-AUG-2009 at 21 weeks ultrasound for survey of anatomy revealed normal female, on an unspecified date amniocentesis revealed fetus, on 23-JUL-2009 MSAFP for screening for anomalies revealed WNL. On approximately 22-DEC-2009 the patient experienced protracted labor as complication during labor/delvery. On 22-DEC-2009 the patient delivery a normal female infant with weight 6 pound 13 oz, length 19.5 inch, Apgar score 7/9, head circumference 14 inch. The weeks from LMP we

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 06/23/09, for survey anatomy at 13 weeks revealed normal female; ultrasound, 08/18/09, for survey anatomy at 21 weeks revealed normal female; amniocentesis, fetus; urine beta-human, ?/?/09, positive; serum alpha-fetoprotein, 07/

History:

Prex Illness: Pregnancy NOS (LMP=3/25/2009); Obesity

Prex Vax Illns:

Vaers Id: 387154-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Aug-2007	30-Jul-2009	699	11-May-2010	12-May-2010	MD	WAES0909USA04916	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse for GARDASIL, a pregnancy registry product, concerning a 19 year old female patient with medical history of smoke and might have conceived on NUVARING, plan B who on 31-AUG-2007 was vaccinated IM with 0.5 ml dose of GARDASIL (Lot#661846/1312X) at left deltoid. There was no concomitant medication. On 21-AUG-2009 the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL. On 31-AUG-2009 the patient took a urine home pregnancy test and it was positive. The patient came into the office for a pregnancy visit on 22-SEP-2009. On this visit ultrasound performed and estimated due date would be 05-MAY-2010. The last menstruation period was approximately 31-JUL-2009. The patient was not experiencing any problems, there were no adverse effects report. Follow up information has been received from the nurse who reported that on 20-OCT-2009 the patient called to cancel her appointment. Message stated cancellation due to possible miscarriage or termination of pregnancy. No further information noted. On 19-NOV-2009, the nurse left a message for the patient to call the office. There was no follow up phone calls from patient. The nurse was unable to contact again in April 2010 because the phone number is no longer in service. There was no further information and none was anticipated. Possible miscarriage or termination of pregnancy was considered to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: ultrasound, 09/22/09, due date would be 06-MAY-2010; urine beta-human, 08/31/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = 7/31/2009); Smoker; Contraception

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: 387157-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	15-May-2009	Unknown		11-May-2010	12-May-2010	FR	WAES1005USA00147	27-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Demyelination, Hypoaesthesia, Monoparesis

Symptom Text: Information has been received from a Health Authority (ref. # GR-EOF-91689), via VIANEX (ref. # SPV10021), concerning a 22 year old female patient who on 15-MAY-2009 received a second single dose of GARDASIL (lot #, batch # and site of administration not reported) via intramuscular route. The patient presented right leg paresis and left arm numbness a few days after the second dose of GARDASIL. The symptoms lasted for approximately 1 week. Brain and cervical MRI was performed in June 2009, showing multiple demyelinating foci. CSF electrophoresis showed oligoclonal IgG. The outcome of the reactions was not reported. Previous MRI, performed in November 2008, was normal. The patient had a history of right arm paresis in June 2007 (duration 1 month), facial nerve paresis in June 2008 (duration not specified), diplopia in November 2008 (duration 5 days) and leg paresis. The patient had received a first dose of GARDASIL on 15-MAR-2009. No concomitant medication was reported. This report is serious due to patient was hospitalized (dates not reported). Other business partner numbers include E2010-02836. Additional information has been requested.

Other Meds: None

Lab Data: magnetic resonance imaging, ??Nov08, normal; magnetic resonance imaging, ??Jun09, brain and cervical MRI showed multiple demyelinating foci; CSF protein electrophoresis, ??Jun09, showed oligoclonal IgG

History: Leg paresis; Facial paresis; Diplopia; Right arm paresis

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387158-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-May-2010	12-May-2010	FR	WAES1005USA00364	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Depression, Hyperventilation, Vaccine positive rechallenge

Symptom Text: Information has been received from a general practitioner concerning a female patient of unspecified age who was vaccinated with the third dose of GARDASIL (lot number not reported) on an unspecified date. Approximately four weeks after first vaccination with GARDASIL the patient experienced physical symptoms such as depression, anxiety and hyperventilation. After the second dose she developed an aggravation of the same symptoms. After her third vaccination the symptoms aggravated again and she was hospitalized. The reporter pointed out that the patient had these episodes in "certain intervals". After patient became pregnant (date unknown) she developed the symptoms again. At the time of reporting the patient had not recovered. Other business partner numbers include: E2010-02851. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387159-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-May-2010	12-May-2010	NY	WAES1005USA00437	12-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Laboratory test, Nervous system disorder, Wheelchair user

Symptom Text: Information has been received from a physician who reported that one of his patient's mother mentioned that at some point last year, in 2009, a young woman was vaccinated with a dose of GARDASIL (lot # not reported) and the patient developed neurologic disorders. Unspecified medical attention was sought. The patient went through many tests and was currently in a wheelchair. At the time of this report, the patient's outcome was unknown. Neurologists did not believe that it was due to receiving GARDASIL. Neurologic disorder was considered to be disabling by the reporter. Attempts to verify the existence of an identifiable patient have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387160-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		11-May-2010	12-May-2010	--	WAES1005USA00536	12-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Autopsy, Death, Headache

Symptom Text: Information has been received from a physician who found out from another treating physician who was also the father of the patient, concerning a 16 year old female patient who on an unknown date, was vaccinated with a dose of GARDASIL. Subsequently the patient developed a severe headache. Then the patient went to sleep that night and passed away. The autopsy was performed which revealed no cause of death. It is unknown if the patient sought medical attention. Severe headache was considered to be immediately life-threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387180-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-May-2010	03-May-2010	0	11-May-2010	11-May-2010	WA		11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU(H1N1)	SANOFI PASTEUR	UF486AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1099Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness

Symptom Text: Client passed out in Lobby - witness stated didn't hit head - had reached for chair then fell to floor. Had the 2 immunizations and a blood draw. States fainted after blood donation in the past.

Other Meds: None Known

Lab Data: EKG

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387185-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-May-2010	03-May-2010	0	11-May-2010	11-May-2010	IL		21-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3045AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Local reaction, Swelling

Symptom Text: Local reaction. 8cm by 9cm area redness. Slight swelling.

Other Meds: NUVA RING

Lab Data: None

History: seasonal; environmental allergies

Prex Illness: None.

Prex Vax Illns:

Vaers Id: **387192-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-May-2010	10-May-2010	0	11-May-2010	11-May-2010	NC		26-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1300Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect route of drug administration

Symptom Text: VACCINE ADMINISTERED IM INSTEAD OF SC-NO REACTION TO VACCINE.

Other Meds: ZOLOFT 50 MG QD, SEASONALE OCP QD

Lab Data: NO

History: ANXIETY DISORDER, ALLERGIC RHINITIS, TRICHOTELAMANIA

Prex Illness: NO

Prex Vax Illns:

Vaers Id: 387214-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	06-May-2010	09-May-2010	3	11-May-2010	11-May-2010	NY		11-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	DTAP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymph node pain, Lymphadenopathy, Tenderness

Symptom Text: Felt soreness in clavicular lymphnode near collarbone. One felt tender and quite enlarged, another was smaller but also tender. Both nodes located on right side of neck, close to collarbone, but not on the collarbone. Felt less sore the day after, so it seems to be getting better and returning to normal, though the node is still enlarged.

Other Meds: Adderall Vyvanse Ocella

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387221-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-May-2010	07-May-2010	0	11-May-2010	12-May-2010	CA		27-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1558Y	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	U3035AA	5	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3069AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1378Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Patient passed out after receiving multiple vaccines. Lasted one (1) minute regained consciousness. Reported to MD. No orders or treatments made. No injuries noted.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387233-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Apr-2010	13-Apr-2010	0	12-May-2010	13-May-2010	FR	WAES1005USA00365	13-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-822342241) concerning a 13 year old female patient who on 13-APR-2010 received a dose of GARDASIL (batch number not reported, site of administration not reported) by intramuscular route. Minutes after vaccination, the patient suffered convulsions and syncope. The patient recovered the same day, on 13-APR-2010. Case was reported serious by the Health Authority, with other medically important condition as criteria. Other business partner numbers include: E2010-02898. Case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **387239-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	09-Sep-2008	09-Sep-2008	0	12-May-2010	13-May-2010	NJ	WAES0810USA04882	13-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arrested labour, Caesarean section, Cephalo-pelvic disproportion, Drug exposure during pregnancy, Mastitis, Pyrexia

Symptom Text: Information has been received from a health professional for the Pregnancy Registry for GARDASIL concerning a 26 year old female who on an unspecified date was vaccinated with the first dose of GARDASIL. On 09-SEP-2008 was vaccinated with a second dose of GARDASIL. The patient is pregnant. On 22-OCT-2008, an ultrasound was performed to the patient in order to determine estimated gestational age (EGA) and the results showed, intrauterine pregnancy (IUP) of 8 weeks (LMP was on approximately 27-AUG-2008 and estimated delivery date: 03-JUN-2009). The patient has not had previous pregnancies. In August 2008, a status post colposcopy showed a negative biopsy and negative for herpes simplex 2 (HSV2). Follow up information received from a physician indicated on 21-MAY-2009 at 40 weeks from her last menstrual period the patient gave birth to a normal male, who weighted 8 pounds and 7 ounces; his Apgar score was 8/9. During the labor the patient experienced maternal fever. Follow up information received from a health worker indicated that the patient had a normal pregnancy without complications and that the patient delivered a healthy male without congenital defects. Follow up information indicated that the patient had a C-section on 21-MAY-2009; the physician who delivered the patient's baby indicated that the patient had a "term pregnancy, arrest descent, fetal tachycardia and maternal fever"; it was also confirmed that the patient had cephalopelvic disproportion. It was also reported that on 22-JUN-2009 the patient had a follow appointment with the physician for an incision check and the patient had recovered. On 29-JUN-2009 the patient had a follow up visit with the physician. The patient was diagnosed with mastitis of the left breast. The reporter did not know if the patient recovered from mastitis. The patient had cancelled her follow up appointment scheduled for July 2009. Upon internal review, cesarean section due cephalopelvic disproportion was considered an other important medical event. The baby's experience has

Other Meds: Unknown

Lab Data: ultrasound, 10/22/08, Estimated gestational age (EGA): + IUP 8 weeks; colposcopy, 08/??/08, biopsy (-), HSV 2 (-); Apgar score, 05/21/09, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 8/27/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387276-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	M	07-May-2010	08-May-2010	1	12-May-2010	12-May-2010	WI		27-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	117Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Nausea, Vomiting

Symptom Text: Nausea, vomiting, & diarrhea. Did not have an elevated temp. per parent.

Other Meds:

Lab Data:

History: No

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387279-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	29-Apr-2010	30-Apr-2010	1	12-May-2010	12-May-2010	WI		21-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	A4AVB327AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash vesicular

Symptom Text: Imm on 4/29 - macro-vesicular rash inside (L) elbow- 4/2-spread to rash - also spread to inside (R) knee 5/6/10 & (R) cheek today.

Other Meds:

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387293-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	15-Jan-2010	15-Jan-2010	0	12-May-2010	12-May-2010	PA		21-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Urticaria

Symptom Text: Hives approximately 2-3 hours after and continuous headache/"migraine" per patient for 2 months.

Other Meds: LOESTRIN 1.5/30; PRISTIQ

Lab Data: None

History: Migraines; depression

Prex Illness: No

Prex Vax Illns:

Vaers Id: **387312-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	10-May-2010	10-May-2010	0	12-May-2010	13-May-2010	CA		13-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Chest pain, Decreased appetite, Discomfort, Sensation of pressure

Symptom Text: Chest/upper abdominal pain/discomfort (crushing feeling), does not radiate and occurs intermittently. Decrease in appetite.

Other Meds: Microgestin Fe

Lab Data:

History: Allergy to pet dander and dust mites, codeine and opiate derivatives

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387335-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-May-2010	03-May-2010	0	13-May-2010	13-May-2010	TX		07-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3352AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3054AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1353Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Pt received shots, TDAP, MCV4 and HPV on 5/3/10, pt stated had her last menstrual period on 4/27/10, and had no suspicion of pregnancy on prequestionnaire before shots given. On 5/2/10 received a call from pt mom stating pt revealed on today is pregnant.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387344-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Apr-2007	09-Apr-2007	0	13-May-2010	13-May-2010	PA		19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U1932AB	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0244Y	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2609AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chromatopsia, Dizziness, Visual impairment

Symptom Text: Patient stated she had trouble seeing for a few mins, color changed, dizzy.

Other Meds: None

Lab Data:

History: Charcot-Marie-Tooth disease 32 Dx 9/09

Prex Illness: None

Prex Vax Illns:

Vaers Id: **387355-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		13-May-2010	14-May-2010	FR	WAES1005USA00700	14-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Demyelination, Ophthalmoplegia

Symptom Text: Initial information received on 04-MAY-2010 through a company representative and a health care professional, a family planning physician, regarding a 23 year old female who was administered the first dose of GARDASIL (Batch, route and site of administration not reported) on an unspecified date. It was reported that 15 days after vaccination the patient suffered ocular paralysis. A CT scan was performed (date not reported). Some more dense spots were found in white matter. A nuclear magnetic resonance was performed and a demyelination process was detected. The patient was not hospitalized. Medical history: It was notified that two test were performed two years ago and one year ago with normal results (dates not reported). This year (2010) a new PAP smear test was performed, a HSIL was detected (diagnosis date not reported). Also, a cervical conisation was performed (date not reported). Therefore, the physician recommended her to be vaccinated against human papillomavirus. The physician thought that these adverse events were not related with GARDASIL. However, the neurologist who saw the patient thought that there was a connection with the vaccination (this information was provided by the family planning physician). At the time of reporting the patient had not recovered. More clinical test were performing, but at the time of reporting the results were not available. The pharmacovigilance department considered this case as serious with other important medical condition. No further information was reported. Other business partner numbers include E2010-02940.

Other Meds: Unknown

Lab Data: computed axial tomography, ??10, dense spots were found in white matter; magnetic resonance imaging, ??10, demyelination process was detected; Pap test, ??10, a HSIL was detected; Pap test, normal (two PAP were normal)

History: Cervical conisation

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387390-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-May-2010	13-May-2010	0	13-May-2010	13-May-2010	WI		14-May-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3090AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Child sitting on floor & fainted. Approximately 10 minutes after immunization.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387391-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-May-2010	11-May-2010	0	13-May-2010	13-May-2010	GA		27-May-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3091AA	0	Right arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B052AA	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash generalised

Symptom Text: Rash on face then all over body within hours of vaccination. Itching began 05/11/2010.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387395-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-May-2010	12-May-2010	0	13-May-2010	13-May-2010	WA		14-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1316Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Pt passed out after recieving first dose of HPV.

Other Meds:

Lab Data: na

History: none known

Prex Illness: none known

Prex Vax Illns:

Vaers Id: **387407-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	13-May-2010	13-May-2010	0	13-May-2010	14-May-2010	TX		21-May-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1710Y	1	Right arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U3075AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB349AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle twitching

Symptom Text: Pt had involuntary twitches of body, due to receiving vaccine. Pt received BENADRYL 50mg 1mL to buttock. Twitches more in Rt leg and Lt arm. Vitals 136/93 P 83 O2 99% vitals were rechecked after 15 min BP 125/80.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 387416-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Mar-2010	08-Apr-2010	20	13-May-2010	14-May-2010	CA		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1378Y	1	Right arm	Unknown	HPV4

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Chills, Headache, Loss of consciousness, Lumbar puncture, Malaise, Musculoskeletal stiffness, Nausea, Neurological examination normal, Pain, Pyrexia, Viral infection, Vomiting

Symptom Text: This was the 2nd in the HPV series of shots. My daughter had terrible headaches and was throwing up three days after her first vaccine. She never ran a high fever, and missed a week of school. Three weeks to the day after her 2nd shot she began to fill ill. Headache, body ache etc. By the following afternoon she had a stiff neck, the "worst headache she had ever had". We were out of town and she insisted we see a doctor instead of self treat at the hotel. We went to a walk in center where they recorded a low grade fever (101) and because of the stiff neck and headache sent us to the ER for fear of meningitis. My daughter was kept in the ER overnight and given morphine for the pain, had spinal fluid taken, blood tests run etc. She was admitted to the Pediatric Ward where she remained until Tuesday, April 13th. She was tested for Strep Throat, neurological disorders, mono, migranes etc. She was finally released when the doctors felt like we could handle her headache pain with prescriptions and then over the counter medicines. The only thing offered us was it was "viral". The initial doctor in the PED Ward said it was her 3rd case with these symptoms - all coming in looking like meningitis initially - with no conclusions being drawn after a battery of tests. The following information was obtained through follow-up and/or provided by the government. 5/19/2010 PCP ovs 3/18 and 4/14/2010, Dx headache patient with c/o's sudden onset severe headaches, nausea, achiness, chills, passed out am 4/14, seen in ED x 2, neuro exam wnl, neurologist did not think was a migraine, had a LP, labs and dx studies wnl

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 5/19/2010 PCP ovs 3/18 and 4/14/2010, Dx headache Labs: mono and strep tests negative, csf wnl Dx studies: CT head wnl

History: none known The following information was obtained through follow-up and/or provided by the government. 5/19/2010 PCP ovs 3/18 and 4/14/2010, Dx headache PMH: None Allergies: NKDA

Prex Illness: none known The following information was obtained through follow-up and/or provided by the government. 5/19/2010 PCP ovs 3/18 an

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387417-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-May-2010	12-May-2010	2	13-May-2010	14-May-2010	TX		14-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling, Paraesthesia oral

Symptom Text: Swollen & tingling lips.

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **387537-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Jan-2009	01-Sep-2009	242	14-May-2010	17-May-2010	IN		25-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Amnesia, Arthralgia, Blindness transient, Chest pain, Convulsion, Decreased appetite, Dizziness, Fatigue, Hypoaesthesia, Insomnia, Migraine, Muscular weakness, Myalgia, Pain in extremity, Paralysis, Pruritus, Rash, Syncope, Weight decreased

Symptom Text: Last dose of Gardasil was administered in January, 2009. Adverse symptoms include: Migraine headaches, dizziness, lightheadedness, chronic fatigue, seizures, intermittent paralysis, numbness in lower extremities, leg pain, temporary loss of vision, muscle weakness, fainting spells, memory loss, joint pain, muscle pain, hair loss, chest pain, appetite loss, loss of weight, insomnia, itching and rashes.

Other Meds:

Lab Data: Blood work, MRI's, CT scans, x-rays, EEG & EMG - all came back within normal limits.

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387559-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-May-2010	10-May-2010	0	14-May-2010	17-May-2010	AL		22-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB362AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	UF500CA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1330Y	0	Left arm	Intramuscular	
FLU(H1N1)	SANOFI PASTEUR	UP055AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1318Y	2	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3046AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling hot, Hyperhidrosis, Hypotension

Symptom Text: Approx 8 min after receiving seven vaccines pt began complaining of feeling dizzy. She then slumped to her knees saying she was going to pass out. A code blue was called and Dr. immediately responded. Pt had already been assisted to a chair. She was perspiring and c/o feeling hot. Dr. gave her Gatorade to drink and ordered Glu which was 97 and Hgb (15.2) BP initially 66/40, 5 min later 70/42. She was asked to put her head between her knees. She began to feel better after 15 min later. She walked to exam room to finish her visit.

Other Meds: None

Lab Data: BP 66/40 - 5 min later 70/42; P - 72; Glucose - 97; Hemoglobin - 15.2

History: None known

Prex Illness: Cough; stuffy nose

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387565-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-May-2010	13-May-2010	0	14-May-2010	17-May-2010	CA		09-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3076AA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	0672Y	0	Unknown	Intramuscular	
TDAP	SANOFI PASTEUR	C3352AA	0	Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	1457Y	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Syncope

Symptom Text: 11 y/o female patient, was being given MENACTRA, Varicella Tdap, GARDASIL. While administering HPV vaccine, patient fainted with some jerky movement x 7 secs., regain consciousness. No drooling No incontinence noted.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 387592-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	22-Feb-2010	03-Mar-2010	9	17-May-2010	18-May-2010	FR	WAES1005ZAF00002	16-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Disorientation, Encephalitis, Meningitis viral, Migraine, Vertigo

Symptom Text: Information has been received from a physician via a company rep concerning an approximately 22 year old female with a history of skin lesion who on 22-FEB-2010 was vaccinated with GARDASIL. On 03-MAR-2010 the patient complained of a severe headache/migraine like. On 05 March 2010 she developed vertigo and her mother found her on the floor disorientated. The patient was taken to an emergency room where she was seen by a physician. The patient was admitted to hospital where an uncomplicated viral meningitis/encephalitis was diagnosed. A positive serology for Epstein Barr Virus was found. Her bloods showed an increase in white blood cells with a mild increase in the SSV protein. No other intracranial pathology was seen. She had a Glasgow come scale of 15/15. An EEG showed a possible global cerebral dysfunction. The patient's recovery was uncomplicated, her symptoms were treated. She recovered from the viral meningitis/encephalitis. The reporter felt that the viral meningitis/encephalitis was not related to therapy with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: electroencephalography, 05?Mar10, Possible global cerebral dysfunction; Diagnostic laboratory test, 05?Mar10, Positive serum for EPSTEIN BARRE Virus; WBC count, 05?Mar10, Mild increase in SSV protein; Glasgow coma scale, 05Mar10, 15, 15

History: Skin lesion

Prex Illness:

Prex Vax Illns:

Vaers Id: 387593-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Apr-2010	19-Apr-2010	0	17-May-2010	18-May-2010	--	WAES1005USA00288	18-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Diarrhoea, Dizziness, Dyskinesia, Fatigue, Headache, Injection site pain, Loss of consciousness, Nausea, Paraesthesia, Pyrexia, Reaction to previous exposure to any vaccine

Symptom Text: Information has been received from a physician, a medical assistant and the patient's mother concerning, a 15 year old female with no medical history or drug reaction/allergies reported who on 19-APR-2010 was vaccinated with a dose of GARDASIL (lot n. 663573/0969Y), 0.5 mg. Concomitant therapy included LOESTRIN. The patient's mother stated that her daughter was given GARDASIL on 19-APR-2010, and this date, she "jerked" within 20 seconds and then she passed out and her blood pressure dropped precipitously. She came to and had nausea and tenderness at the injection site. She started feeling dizzy and had a 102 degree fever for 4 hours. Her extremities started tingling and she had diarrhea on days 3 and 4 following injection, and she had fatigue for first 72 hours. At the time of reporting, the patient still had bouts with dizziness and nausea and she passed out again on 03-MAY-2010. On 04-MAY-2010, the patient experienced headache. Subsequently, the physician stated that the patient received the first dose of GARDASIL and experienced syncope with seizure like movement of the arms and legs about 15 seconds. Physician felt as though it is related to GARDASIL. Later, the medical assistant reported that the patient experienced syncope then, tonic clonic movements. She stated that the physician did not feel this was a seizure (conflicting information with physician's information). The event was not disabling or life threatening and patient did not need to go to the emergency room. Treatment included an antiemetic and increased fluid intake. At the time of reporting the patient was still recovering. Upon internal review syncope with seizure like movement of the arms and legs was considered to be an other important medical event. Additional information has been requested.

Other Meds: LOESTRIN

Lab Data: body temp, 04/19/10, 102 deg

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **387594-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Jan-2010	28-Apr-2010	96	17-May-2010	18-May-2010	FR	WAES1005USA01063	18-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician via the Program for Appropriate Technology concerning an 11 year old patient who on 21-JUL-2009 and 09-OCT-2009 was vaccinated with a first and second dose of GARDASIL respectively (routes, site of injection and lot numbers not reported). On 22-JAN-2010, the patient received her third dose of GARDASIL respectively (route, site of injection and lot number not reported). Subsequently, the patient died on 29-APR-2010, 96 days after the patient received her third dose. Additional information has been expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387595-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Apr-2008	Unknown		17-May-2010	18-May-2010	FR	WAES1005USA01078	18-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Autonomic nervous system imbalance, Chest pain, Dizziness, Dyspnoea, Fatigue, Nausea, Oropharyngeal pain, Pharyngitis, Syncope

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail concerning a 14 year old female patient who on 04-APR-2008 was vaccinated with a dose of GARDASIL (lot number not reported). Subsequently the patient experienced fatigue, nausea, dizziness, antonomic instability, fainting, breathlessness, pain in stomach, chest, sore throat and recurrent throat infections. The patient was graded return to activity. At the time of the report, the patient had not yet recovered. The reporter felt that fatigue, dizziness, pharyngitis and syncope were possibly related to GARDASIL. Fatigue, dizziness, pharyngitis and syncope were considered to be disabling. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387598-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Mar-2010	15-Mar-2010	0	17-May-2010	18-May-2010	FR	WAES1005USA01120	18-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ29410		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cardiac monitoring, Cardio-respiratory arrest, Electrocardiogram, Pallor, Pulse absent, Syncope, Unresponsive to stimuli

Symptom Text: Information was obtained on request by the company from the agency via public case details form concerning a 12 year old female patient who on 15-MAR-2010 was vaccinated with one dose of GARDASIL (Lot # NJ29410 and Batch # NK30260) intramuscularly. It was reported that on 15-MAR-2010, the patient collapsed within 7 minutes of receiving the vaccine. The patient was pale, no carotid pulse and non responsive. The patient was admitted to the hospital and received CPR and intramuscular adrenaline at school, an ECG was performed (results not provided) and cardio respiratory monitoring for 6 hours. The event caused the patient's hospitalization. It was reported that on 15-MAR-2010 the patient recovered from cardio-respiratory arrest. The agency considered that cardio-respiratory arrest was possibly related to vaccination with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387599-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	06-May-2010	08-May-2010	2	17-May-2010	17-May-2010	WI		17-May-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1106Y		Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3090AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site rash, Rash erythematous

Symptom Text: Fine red raised rash at site of injection - L deltoid. Rash spread up to shoulder. MD perscribed cortizone cream to affected area.

Other Meds:

Lab Data:

History: NO

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387601-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Sep-2009	19-Sep-2009	2	17-May-2010	17-May-2010	OH		26-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	0476Y	0	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Skin warm

Symptom Text: Got a huge baseball size hard red hot spot on her arm. Was very sore. No fever. Lasted started Thursday night, worse Friday and over the weekend. Lasted approximately 5 days, warm compresses.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387602-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-May-2010	11-May-2010	0	17-May-2010	17-May-2010	AZ		18-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU(H1N1)	SANOFI PASTEUR	UP066AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1099Y	2	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1155Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased

Symptom Text: Mother stated that "last night my daughter had a lot of temperature, and now it is 101.5" Denies N/V. Advised to give fever reducing meds, increase H2O.

Other Meds: No

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387618-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Apr-2010	12-Apr-2010	0	17-May-2010	18-May-2010	FR	WAES1005USA01200	18-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ49370	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diarrhoea, Headache, Rash scarlatiniform, Somnolence, Vertigo, Vomiting

Symptom Text: Information has been received from a Health Authority (case # 116416) (local case #IT218/10) concerning an 11 year old female patient who on 12-APR-2010 was vaccinated with the second dose of GARDASIL (LOT # NJ49370 and Batch # NK44500) intramuscularly. It was also reported that twenty days following the administration of the first dose of vaccine, the patient presented with scarlet fever like exanthema (throat culture negative) and repeated watery vomiting that resolved after infusion therapy within 24 hours. On the same day, 1 hour post-vaccination, she presented with significant somnolence and headache, followed after another 1 hour by 2 vomiting episodes and 2 episodes of diarrhea. The patient was admitted to the hospital. A brain MRI was performed on 15-APR-2010 and was negative, an EEG performed on the same date showed a prevalence of sporadic sharp-waves to the left. The headache, the somnolence and diarrhea resolved on 12-APR-2010 with onset two days post vaccination of vertigo syndrome and persistence of the vomiting episodes (3-5 daily). The health authority coded diarrhea, headache, somnolence, peripheral vertigo unspecified and vomiting. The final outcome was recovered on 17-APR-2010. Other business partner numbers include: E2010-03039. No further information is available. The case was closed.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 15Apr10, negative; electroencephalography, 15Apr10, showed a prevalence of sporadic sharp-waves to the left

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **387633-1** **Related reports:** 387633-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-May-2010	11-May-2010	0	17-May-2010	18-May-2010	PA		19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0075Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Angioedema, Dyspnoea, Erythema, Swelling, Throat tightness, Urticaria

Symptom Text: Within 5-10 minutes of given GARDASIL vaccine patient developed urticaria and angioedema of face, cheeks, ears. Patient also complained of throat tightness and sense of difficulty breathing. Erythema also developed of face and progressively spread with swelling to neck and chest. Epi 0.2cc given subcut. with notable improvement.

Other Meds: No routine medications

Lab Data: None

History: No well child

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387633-2** **Related reports:** 387633-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-May-2010	11-May-2010	0	20-May-2010	21-May-2010	PA	WAES1005USA01463	21-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0075Y	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Condition aggravated, Rash generalised, Syncope, Tremor, Urticaria

Symptom Text: Information has been received from an office manager concerning a 12 year old female patient with no known drug reactions or allergies and no pertinent medical history who on 03-SEP-2009 was vaccinated IM with the first 0.5ml dose of GARDASIL (Lot # 661953/1130X), on 11-JAN-2010, was vaccinated IM with the second 0.5ml dose of GARDASIL (Lot # 663558/0819Y) and on 11-MAY-2010 was vaccinated IM with the third 0.5ml dose of GARDASIL (Lot # 661954/0075Y). It was reported that on 11-MAY-2010, the patient developed hives within 5 to 7 minutes of receiving the third dose of GARDASIL. The patient also experienced a general rash, shakiness, weakness and syncope. The patient was treated with BENADRYL oral, subcutaneous epinephrine and inhaled albuterol. The patient's symptoms improved temporarily then her symptoms became worse. The patient was sent to the emergency room. The patient was not admitted to the hospital. At the time of the report the patient had recovered. The reporter was not admitted to the hospital. At the time of the report the patient had recovered. The reporter stated that since she had 2 other patients (WAES# 1005USA01505 and WAES# 1005USA01536) that experienced an adverse event after administration of GARDASIL with Lot # 661954/0075Y on the same day within 4 hours she was not comfortable using the GARDASIL. There were no laboratory tests performed. The office manager requested a lot check. This is one of several reports received from the same source. A lot check has been initiated. Upon internal review the patient's urticaria and generalized rash, treated with subcutaneous epinephrine were considered to be other important medical events. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **387634-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-May-2010	04-May-2010	0	17-May-2010	18-May-2010	MI		19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB167BA	1	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1333Y	1	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U3088AA	0	Unknown	Intramuscular	
	IPV	SANOFI PASTEUR	D01222	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Concussion, Contusion, Dizziness, Excoriation, Fall, Loss of consciousness, Tunnel vision

Symptom Text: Following vaccination patient got up from table and started to feel lightheaded w/ tunnel vision and blackening. Patient then fell to floor, w/o loss of consciousness. Resulted in child abrasion, contusion on left side of face and mild concussion. Patient released from clinic w/ f/u appointment in 2 days.

Other Meds: TYLENOL #3; bupropion XL; clindamycin 1% topical; LOESTRIN

Lab Data: None

History: Depression; acne; irregular menstruation

Prex Illness: Stayed home from school 2/2 not feeling well

Prex Vax Illns:

Vaers Id: **387658-1 (S)** **Related reports:** 387658-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Nov-2009	25-Jan-2010	63	17-May-2010	18-May-2010	IL		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Mastication disorder, Muscular weakness, Myasthenia gravis

Symptom Text: Muscle weakness which was ultimately diagnosed at myasthenia gravis. The following information was obtained through follow-up and/or provided by the government. 05/20/10. Progress notes 11/23/09, 3/22/10. Pt c/o muscle weakness, weakness of BLE and BUE, chewing problems. Assessment: bilateral knee and hand weakness with pain, questionable etiology, acne. On 04/30/10, LE weakness progressing. On 05/13/10, Pt diagnosed with myasthenia gravis generalized. Pt to have thymectomy in the future.

Other Meds:

Lab Data: Elevated Acetylcholinesterase antibody with confirmatory tensilon test at neuromuscular specialist The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: red blood cells 5.32/ul (H);

History: The following information was obtained through follow-up and/or provided by the government. PMH and allergies: none.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387658-2** **Related reports:** 387658-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Nov-2009	01-Jan-2010	39	16-Jul-2010	19-Jul-2010	IL	WAES1005USA01583	19-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscular weakness, Myasthenia gravis

Symptom Text: Information has been received from a nurse concerning a patient who was vaccinated with a dose of GARDASIL. Subsequently the patient experienced an adverse experience, but did not mention what the experience was. At the time of the report, the patient's outcome was unknown. It was unknown if the patient sought medical attention. Follow up information has been received from a nurse who reported that the 12 year old female patient with no illness at the time of vaccination, on 23-NOV-2009 was vaccinated intramuscularly with the second dose of GARDASIL (lot # 660612/0229x). On 01-JAN-2010 the patient experienced muscle weakness which was diagnosed as myasthenia gravis. Myasthenia gravis was considered to be an other important medical event due to medical/surgical intervention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 387662-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	12-Mar-2010	28-Mar-2010	16	17-May-2010	18-May-2010	FL		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y		Right arm	Intramuscular	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Alopecia, Arthralgia, Back pain, Erythema, Fatigue, Hyperaesthesia, Malaise, Muscular weakness, Musculoskeletal stiffness, Nuchal rigidity, Paraesthesia, Post lumbar puncture syndrome, Reflexes abnormal, Vitamin B12 deficiency

Symptom Text: SKIN SENSITIVITY. SECOND DAY-LEG WEAKNESS. THIRD DAY-COULDN'T MOVE NECK. FOURTH DAY COULDN'T WALK AND WAS ADMITTED TO THE HOSPITAL. The following information was obtained through follow-up and/or provided by the government. 05/20/10. PCP visit on 03/12/10. DX: asthma. Pt received immunization. Pt discharged home in good condition. DC summary 04/02/10-04/08/10. Pt unable to walk, had paresthesias, pain and weakness of ankles, joint pain to touch, alopecia. DX: malaise and fatigue, B12 deficiency, asthma. 05/25/10. Neurology consult note for DOS 04/10/10. Pt developed orthostatic headache, dizziness, foot numbness, sensory problem and weakness, stiff neck, low back pain after lumbar puncture, forgetfulness, hypoactive reflexes. Pt has palmar redness, facial redness. Assessment: neurologist considered GBS and dermatomyositis. On 04/22/10, EMG/NCS studies were normal and showed no evidence of demyelinization.

Other Meds: ADVAIR

Lab Data: MRI- UPPER BODY; CT SCAN UPPER BODY AND LUNGS; NERVE CONDUCTION The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: spine X-ray: narrowing of L5-S1. WBC 17,000 (H), CSF negative.

History: The following information was obtained through follow-up and/or provided by the government. PMH: chronic asthma, shortness of breath, ovarian cyst. Allergies: NKDA.

Prex Illness: NO

Prex Vax Illns:

Vaers Id: 387666-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-May-2010	14-May-2010	0	17-May-2010	19-May-2010	AZ		19-May-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3077AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1013Y	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B053BB	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1111Y	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaccination complication

Symptom Text: Received 4 vaccines - asked to sit in chair x 15 min after HPV- stay next to pt admin (R) arm - after 2 min walk to chair to continue vaccine. Saw pt lean to (R) can get it lower to floor - after several seconds open eyes -talking no sign of injury with nurse x 10 min - given Panar Barrett wash - Denies having anything - no sign of injury. Ambulated to school nurse office. Dad called and made aware to call PM and to doctor. Pt denied any problems. 3 friends gave lunch stayed with in office -"Im fine". 5/17/10 called and spoke with pt Dad. 15:40 - Pt's fine "120" didn't feel well @ 1st and pt snapped out of it She is fine".

Other Meds: None

Lab Data: None

History: None known

Prex Illness: No

Prex Vax Illns:

Vaers Id: 387690-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
-0.6	M	Unknown	29-Nov-2008		18-May-2010	19-May-2010	--	WAES0904USA01164B2	19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Circumcision, Continuous positive airway pressure, Drug exposure during pregnancy, Intensive care, Neonatal respiratory distress syndrome, Premature baby, Retinal anomaly congenital, Use of accessory respiratory muscles

Symptom Text: Information has been received from a medical assistant concerning one of twin babies. The baby's 18 year old mother was vaccinated with the first and second 0.5 ml doses of GARDASIL by different provider and was vaccinated IM with the third 0.5ml dose of GARDASIL (lot#: 659962/1740U) on 01-DEC-2008. The mother's last menstrual period was 19-NOV-2008 and estimated delivery date was 05-SEP-2009. The medical assistant reported that the baby was born about 1 month early, in approximately August 2009, but as far as she knew, the baby was born normal and healthy. Follow-up information was received from a pediatrician via medical records. The father of baby (FOB) was a twin. It was reported that the pregnancy complicated by premature rupture of membranes (PROM) and preterm labor, breech presentation and a history of mild pregnancy induced hypertension. The mother received one dose of betamethasone at 23:00 of 12-JUL-2009 and was transferred to another hospital on MgSO4. The mother delivered twin babies (one male and one female) via cesarean section for transverse presentation at 13-JUL-2009. The baby boy was born at 02:07 of 13-JUL-2010, 32 2/7 weeks of gestation, weighing 1690 grams. His head circumference was 27.5 cm and birth length was 45 cm. The apgar score is 9 at 1 minutes and 9 at 5 minutes. The baby boy was vigorous at birth, had decreased air entry and was masked continuous positive airway pressure (CPAP) with Neopuff used. It was reported that the boy developed respiratory distress at birth. On 13-JUL-2009, blood gas capillary revealed PCO2 capillary of 54, PO2 capillary of 53, bicarbonate of 25, O2 Sat of 90, capillary total Hgb of 19.8, capillary oxygen Hgb of 88 and capillary CO Hgb of 1. Chest x-ray revealed hazy and no free air. The baby was transferred to NICU for follow up care. Examination on admission revealed mild to moderate retractions presented in the substernal and intercostal areas, consistent with the prematurity of the baby. Active medications included ampicillin, gentamicin, erythromycin, ey

Other Meds: betamethasone; loratadine; magnesium sulfate

Lab Data: ultrasound, 08/14/09, both hips are within normal limits; ultrasound, 07/20/09, normal ultrasound examination of the neonatal head; chest X-ray, 07/13/09, hazy, no free air; serum direct bilirubin, 07/28/09, 0.5 mg/d; total serum bilirubin,

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387691-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	11-Jun-2009	11-Jun-2009	0	18-May-2010	19-May-2010	--	WAES0906USA05220	19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse, for the Pregnancy Registry for GARDASIL, concerning a 21 year old female who on 26-JUN-2007 was received her first dose of GARDASIL, and the second dose on 11-JUN-2009, and just found out she was pregnant again. No information on status of pregnancy or whether she would continue the pregnancy. Follow up information received from a nurse concerning the patient was seen at their Clinic on 26-Jun-2007, and not again until 11-JUN-2009. On 11-JUN-2009 a urine pregnancy test was performed. And it was negative. Follow up information received from a registered nurse concerning the patient electively terminated the pregnancy for personal reasons, not related to the GARDASIL vaccination. Upon internal review abortion induced was considered an other important medical event. The patient had a history of pregnancy while on prior therapy with the 1st dose of GARDASIL (MSD, WAES#0906USA05568). No further information is available.

Other Meds: Unknown

Lab Data: Urine beta-human, 01/11/09, negative

History:

Prex Illness: Pregnancy NOS (LMP = 5/19/2009)

Prex Vax Illns:

Vaers Id: 387692-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	12-May-2009	12-May-2009	0	18-May-2010	19-May-2010	FR	WAES0907USA00388	19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1882U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Complication of pregnancy, Drug exposure during pregnancy, Foetal disorder, Pre-eclampsia

Symptom Text: Information has been received for the HPV vaccine pregnancy registry from a health professional concerning a 22 year old female patient who received IM the first dose of GARDASIL (batch # NJ0831; lot # 1882U) on 25-MAR-2009 with no adverse effect. The patient was not receiving any concomitant medications. The patient received IM the second dose of GARDASIL (batch # NJ0831; lot # 1882U) on 12-MAY-2009. At the time of receiving the second dose, the patient was pregnant. The last menstrual period date was unknown. At the time of reporting the patient was approximately 12 weeks pregnant. Information has been received from the initial reporter on 06-MAY-2010. The patient received IM the first dose of GARDASIL (batch # NJ0831; lot # 1882U) on 25-MAR-2009 at +/- 6 weeks gestation. The mother received IM the second dose of GARDASIL (batch # NJ08310; lot # 1882U) at +/- 14 weeks gestation. The patient had no medical history or risk factors and was not using recreational drugs or tobacco. The patient had no previous pregnancies. The patient received no diagnostic tests during pregnancy. The patient experienced PET (Pre-eclampsia toxemia) during pregnancy considered as a complication (serious assessment not reported). The case was upgraded serious by the company with OME as seriousness criterion. On 28-SEP-2009 the patient delivered a male baby at 39 weeks of gestation by natural birth and suction with no labour or delivery complications. The outcome for the event of pre-eclampsia toxemia has not been reported. The patient received IM the third dose of GARDASIL (batch # NK31480; lot # NJ28290) on 29-SEP-2009. It has not been reported whether the patient tolerated the dose of GARDASIL. The baby weighed 3.02 Kg and was 54 cm in length with a head circumference of 37 cm and an Apgar score at 1 minute of 10 and at 5 minutes of 10. No malformations or anomalies were diagnosed at birth. The baby had experienced an inguinal hernia repair on an unreported date considered non serious by the reporter. It was not known if the inguinal

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **387693-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	29-Sep-2009	Unknown		18-May-2010	19-May-2010	FR	WAES0907USA00388B1	19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ28290	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Apgar score normal, Drug exposure during pregnancy, Inguinal hernia, Inguinal hernia repair

Symptom Text: Information has been received from the initial reporter on 06-MAY-2010. This case is concerning a male infant who was born on 28-SEP-2009. The patient's mother experienced PET (Pre-eclampsia toxemia) during her pregnancy. The patient was born at 39 weeks of gestation by natural birth and suction with no labour or delivery complications, weighted 3.02 Kg and was 54 cm in length with a head circumference of 37 cm and an Apgar score at 1 minute of 10 and at 5 minutes of 10. No malformations or anomalies were diagnosed at birth. The infant's mother received IM the first dose of GARDASIL (batch # NJ0831; lot #1882U) on 25-MAR-2009 at +/- 6 weeks gestation. The mother received IM the second dose of GARDASIL (batch # NJ08310; lot # 1882U) at +/- 14 weeks gestation. The infant's mother received IM the third dose of GARDASIL (batch # NK31480; lot # NJ28290) on 29-SEP-2009. The baby had experienced an inguinal hernia repair on an unreported date considered non serious by the reporter. It was not known if the inguinal hernia was present at birth. Upon internal review, the case was upgraded to serious by the company with OME as seriousness criterion. Other business partner numbers included E-2010-03025. No further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **387694-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Feb-2010	10-Mar-2010	21	18-May-2010	19-May-2010	FR	WAES1005USA01112	19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Enterovirus infection, Pancreatitis

Symptom Text: Information was obtained on request by the company from the agency via public case details form concerning a 12 year old female patient who on 17-FEB-2010 was vaccinated IM with a dose of GARDASIL (lot number not reported). On 10-MAR-2010, the patient experienced pancreatitis and was hospitalized; treatment included: gut rest and investigation. The following laboratories were performed: rubella/mumps/ Mycoplasma/EBV were negative; enterovirus serology was positive and could be the cause of pancreatitis; WCC scan (?IBD) was normal; sweat test (?CF) was normal and an repeat ultrasound showed no bilary sludge/pathology. ON an unspecified date, the patient recovered from the event. The reporting agency considered that pancreatitis was possibly related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Ultrasound, ??Mar?10, No bilary sludge/pathology; EPSTEIN-BARR virus antibodies, ??Mar?10, Negative; Mycoplasma PCR, ??Mar?10, Negative; WBC count, ??Mar?10, normal, scan (?IBD); serum mumps Ab, ??Mar?10, Negative; serum rubella IgG antibod

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387695-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-May-2010	19-May-2010	FR	WAES1005USA01660	19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia

Symptom Text: An online magazine reported according to a school principal and a physician that six girls with a history of chronic malaria and dysentery (three of six girls) after receiving GARDASIL vaccine were admitted to a hospital complaining of giddiness, headache and numbness. Three of the six girls who were admitted to the hospital were discharged on 05-MAY-2010. It was reported that two of the girls complained of headache on 06-MAY-2010. Meanwhile, two girls also suffered from complications and were admitted to the hospital on 05-MAY-2010. A physician from the hospital said that anxiety, heat and empty stomachs caused the complications. The physician stated that "all girls, who had complications, did not take breakfast and do not bring lunch". But teachers said that, since health officials and teachers had created awareness with students and parents about the vaccine, the girls would not have come to school on empty stomachs. A teacher stated that "it's also compulsory for all students to bring lunch". It was not specified which patients suffered from giddiness, headache and numbness. At the time of the report, the outcome of the patients was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Malaria; Dysentery

Prex Illness:

Prex Vax Illns:

Vaers Id: 387696-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Jun-2008	30-Jun-2008	29	18-May-2010	19-May-2010	FR	WAES1005USA01130	19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Autoimmune disorder, Drug exposure during pregnancy, Gait disturbance, Hypoaesthesia, Infection, Oedema peripheral, Rash erythematous, Scar, Skin burning sensation, Skin lesion, Urticaria, Vasculitis

Symptom Text: Information was obtained on request by the company from the agency via public case details form for the Pregnancy Registry for GARDASIL concerning a 20 year old female with a penicillin, yeast and tomatoes allergies and moderate asthma who on 01-JUN-2008 was vaccinated IM with a first dose of GARDASIL (lot number and site injection not reported). Concomitant therapy included ASMOL and SERETIDE ACCUHALER. It was reported that the patient was eight weeks pregnant at the time of vaccination. On 30-JUN-2008, the patient experienced red spotty rash developing on legs starting around the ankles. With in days it had spread and started to burn and go numb. After a week the patient legs were covered in severe welts and the swelling was so bad she could not walk. After she was admitted to the hospital, some lesions became infected and gangrenous. After wounds healed she was left with significant scarring on her legs. The patient was hospitalized and treated for autoimmune vasculitis. Infected and gangrenous lesions resolved with intravenous antibiotics and steroids (date unspecified). The agency considered that vasculitis was possibly related to therapy with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: ASMOL; SERETIDE ACCUHALER

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Penicillin allergy; Hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387697-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-May-2010	19-May-2010	FR	WAES1005USA01661	19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Dizziness, Headache, Heat illness, Hypoaesthesia, Inadequate diet, Pyrexia, Vaccination complication

Symptom Text: An online magazine reported according to a school principal and a physician that six girls with a history of chronic malaria and dysentery (three of the six girls) after receiving GARDASIL were admitted to a hospital complaining of giddiness, headache and numbness. According to the school principal, two of the six girls suffered from high fever and were taken to hospital for 30 minutes for observation and later referred to the hospital. Three of the six girls who were admitted to the hospital were discharged on 05-MAY-2010. It was reported that two of the girls complained of headache on 06-MAY-2010. Meanwhile, two girls also suffered from complications and were admitted to the hospital on 05-MAY-2010. A physician from the hospital said that anxiety, heat and empty stomach caused the complications. The physician stated that "all the girls, who had complications, did not take breakfast and do not bring lunch". But teachers said that, since health officials and teachers had created awareness with students and parents about the vaccine, the girls would not have come to school on empty stomachs. A teacher stated that "it's also compulsory for all students to bring lunch". It was not specified which patient suffered from giddiness, headache and numbness. At the time of the report, the outcome of the patients was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Malaria; Dysentery

Prex Illness:

Prex Vax Illns:

Vaers Id: 387699-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	27-Apr-2010	01-May-2010	4	18-May-2010	19-May-2010	FL	WAES1005USA01257	19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1377Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Biopsy cervix, Chest pain, Dyspnoea, Urticaria

Symptom Text: Initial and follow-up information has been received from a medical assistant concerning a 23 year old female with prior papilloma viral infection and no known drug allergies who on 27-APR-2010 was vaccinated IM with the first dose of GARDASIL (lot number 665768/1377Y). No other vaccines were administered at the time of the GARDASIL vaccination. At that time, the patient also received Monsel's solution topically to cervical area to stop bleeding, where a biopsy was performed. On 01-MAY-2010 the patient complained of trouble breathing, chest pain and outbreak of hives. The patient was sent to an emergency room (ER, name unknown), where the patient received a cortisone injection. This cortisone treatment was the intervention used to prevent serious criteria. The trouble breathing and chest pains resolved. On 11-MAY-2010, when the office spoke with the patient by phone, the patient was still resolving from the hives. Trouble breathing, chest pain and an outbreak of hives were considered to be other important medical event and disabling by the reporter. The health care professional contacted during telephone follow-up could not supply the following information: hospital name. Additional information has been requested.

Other Meds: Ferric subsulfate (solution)

Lab Data: Unknown

History:

Prex Illness: Papilloma viral infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387700-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		18-May-2010	19-May-2010	FR	WAES1005USA01471	19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Dyspnoea, Headache, Hypoaesthesia

Symptom Text: An online magazine reported according to a school principal and a physician that six girls with a history of chronic malaria and dysentery (three of the six girls) after receiving GARDASIL vaccine were admitted to a hospital complaining of giddiness, headache and numbness. According to the school principal, one of the six girls was a 12-year old student who suffered from breathing problems and was taken to an urgent care facility for 30 minutes for observation and later referred to the hospital. Three of the six girls who were admitted to the hospital were discharged on 05-MAY-2010. It was reported that two of the girls complained of headache on 06-MAY-2010. A physician from the hospital said that anxiety, heat and empty stomachs caused the complications. The physician stated that "all the girls, who had complications, did not take breakfast and do not bring lunch". But teachers said that, since health officials and teachers had created awareness with students and parents about the vaccine, the girls would not have come to school on empty stomachs, A teacher stated that "it's also compulsory for all students to bring lunch". It was not specified which patient suffered from giddiness, headache and numbness. At the time of the report, the outcome of the patient was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Malaria; Dysentery

Prex Illness:

Prex Vax Illns:

Vaers Id: **387701-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		18-May-2010	19-May-2010	FR	WAES1005USA01659	19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia

Symptom Text: An online magazine reported according to a school principal and a physician that six girls with a history of chronic malaria and dysentery (three of the six girls) after receiving GARDASIL were admitted to a hospital complaining of giddiness, headache and numbness. According to the school principal, one of the six girls was a 15 year old student who suffered from leg numbness 30 minutes after receiving the vaccination and was taken for 30 minutes for observation and later referred to the hospital. Three of the six girls who were admitted to the hospital were discharged on 05-MAY-2010. It was reported that two of the girls complained of headache on 06-MAY-2010. A physician from the hospital said that anxiety, heat and empty stomachs caused the complications. The physician stated that 'all the girls, who had complications, did not take breakfast and do not bring lunch". But teachers said that, since health officials and teachers had created awareness with students and parents about the vaccine, the girls would not have come to school on empty stomachs. A teacher stated that "it's also compulsory for all students to bring lunch". It was not specified which patient suffered from giddiness and headache. At the time of the report, the outcome of the patient was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Malaria; Dysentery

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387714-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-May-2010	12-May-2010	1	18-May-2010	18-May-2010	IA		24-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1538Y	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1099Y	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia

Symptom Text: Acute onset of H/A, dizziness and numbness of hands one day after GARDASIL #2 and HEP A#1. Normal neuro exam and treated as migraine with Sumatriptan.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **387720-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Mar-2010	Unknown		18-May-2010	18-May-2010	WA		07-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dizziness, Erythema, Pain, Pruritus, Pyrexia, Rash papular

Symptom Text: Pt had 1) fever x 3 days, 2) itchy, arm bright red & white bump x 2 wks, a couple days later had on both arms, both legs, & feet, & 3) stomach ache pain can't eat & felt like vomiting & dizzy.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: fainted after shot & blood draw~Vaccine not specified (no brand name)~UN~0.00~Patient

Vaers Id: **387724-1** **Related reports:** 387724-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	M	23-Apr-2010	23-Apr-2010	0	18-May-2010	18-May-2010	CO		19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscular weakness, Weight bearing difficulty

Symptom Text: 04/23/10 APX, 10:30 AM received shot Vacline APX 12:30PM inability to bear own weight. Severe muscle weakness. Taken to ER hospital APX 1:45PM muscle began to return to normal. By 3:00PM he seemed back to normal while in ER. Monitoring of vitals-no other treatment.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **387724-2** **Related reports:** 387724-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	M	23-Apr-2010	23-Apr-2010	0	10-Jun-2010	10-Jun-2010	--		13-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscular weakness, Weight bearing difficulty

Symptom Text: At apx 10:30 am received shot vaccine (HPV). 12:30 pm inability to bear own weight - severe muscle weakness. Taken to ER approx. 1:45 pm muscles started to return to normal. By 3:00 pm muscles went back to normal, while in ER monitoring of vitals - no other treatment.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 387752-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Oct-2009	25-Nov-2009	42	18-May-2010	19-May-2010	AZ		22-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	U3204AA		Unknown	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB350BA	1	Right arm	Unknown	
FLU	SANOFI PASTEUR	U3204AA		Left arm	Unknown	
HPV4	MERCK & CO. INC.	0313Y	0	Right arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B040AB	0	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blindness, Cerebrovascular accident, Chromatopsia, Hyperglycaemia, Lumbar puncture normal, Nuclear magnetic resonance imaging abnormal, Obesity, Optic neuritis, Vision blurred, Visual acuity reduced

Symptom Text: Small stroke in left optic nerve - optic neuritis. The following information was obtained through follow-up and/or provided by the government. 5/19, 5/20 & 5/21/10 Hospital records, Ophthalmology consult and discharge summary received for dates of service 11/27/09 to 5/10/10. Dx: Stroke OS eye, optic neuritis OS, L eye vision loss, obesity, hyperglycemia 2/2 steroids. Pt. began experiencing "flashes of light" in the left eye involving the lower visual quadrant. When trying to look out of the L eye only noted vision was blurry with a grayish discoloration at the center of the visual field. Denies pain. Describes it as if it is a strobe light. Seen by an optometrist who noticed pressure on the optic nerve on the left eye. MRI revealed evidence of a swollen left optic nerve. Admitted for further work up including LP and neuro. eval. Decreased vision in left eye on exam. LP revealed normal spinal fluid. Treated with methylprednisolone and discharged on a prednisone taper. Also started on aspirin therapy. At 6 month f/u with Ophthalmology, pt. still had some residual optic neutitis.

Other Meds: None

Lab Data: MRI; Spinal tap; Blood work; VRE; 2nd MRI; Steroids The following information was obtained through follow-up and/or provided by the government. 5/19, 5/20 & 5/21/10 Hospital records, Ophthalmology consult and discharge summary received for

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: 387761-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-May-2010	17-May-2010	0	18-May-2010	19-May-2010	TN		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Computerised tomogram normal, Concussion, Convulsion, Dizziness, Electrocardiogram ambulatory, Fall, Fatigue, Head injury, Headache, Loss of consciousness, Nausea, Oxygen saturation normal, Pain, Pallor, Scan brain, Syncope, Traumatic brain injury, Vomiting

Symptom Text: 1135 AM. Standing up and fainted after vaccine. Hit head on floor. Diagnosed with post impact seizure. Seizure lasted 20 seconds maintained airway, elevated feet. Pulse O2 was 99%. BP stable. Developed nausea/vomited within 2 hours. Sent to ER. Admitted to hosp. with concussion. The following information was obtained through follow-up and/or provided by the government. 5/20 & 5/21/10 Primary care and ED records recieved for date of service 5/17/10. Dx: Syncopal episode, Head injury, closed. After injection apparently fainted, hit head and seized. Sent to ED and evaluated. Pt. c/o HA, dizziness, nausea and vomiting. CT scan of head was unremarkable. Transferred and admitted to another medical facility for observation of concussion. 5/20 & 5/21/10 Primary care and ED records recieved for date of service 5/17/10. Dx: Syncopal episode, Head injury, closed. After injection apparently fainted, hit head and seized. Sent to ED and evaluated. Pt. c/o HA, dizziness, nausea and vomiting. CT scan of head was unremarkable. Transferred and admitted to another medical facility for observation of concussion. 6/9/10 Admission history and physical received for date of service 5/18/10. Dx: Vasovagal syncope, concussion s/p fall, Heacache s/p fall. Admitted for observation, for IV Fluids & for pain control. Pt. with depressed affect, lightheadedness, loss of consciousness, weakness, nausea, headache, tired, pale and non-toxic. 6/23/10 Hospital records and discharge summary received for dates of service 5/18/10 to 5/21/10. Dx: Syncope, Concussion. Pt. had syncope event at PCP office after vaccines, fell and hit head on floor causing a concussion. Had several episodes of vomiting prior to admission. Seen by cardiology, likely vasovagal after shot given. Holter monitor x 24 hours. Concussion resolving. Discharged to home, to follow up with PCP same week.

Other Meds: LEXAPRO 20 mg

Lab Data: CT scan; blood sugar - 97; CBC - WNL The following information was obtained through follow-up and/or provided by the government. 5/20 & 5/21/10 Primary care and ED records recieved for date of service 5/17/10. Labs and diagnostics: CXR-NL,

History: Depression. The following information was obtained through follow-up and/or provided by the government. 6/9/10 Admission history and physical received for date of service 5/18/10. PMH: Heart murmur.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387779-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-May-2010	Unknown		18-May-2010	18-May-2010	VA		19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: no adverse event

Other Meds:

Lab Data:

History: none

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **387831-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-May-2010	Unknown		18-May-2010	19-May-2010	PA		26-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3382AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0229X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Eye rolling

Symptom Text: Lightheaded, eyes rolled but didn't pass out.

Other Meds: CLARITIN

Lab Data:

History: Seasonal

Prex Illness:

Prex Vax Illns:

Vaers Id: **388001-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Aug-2009	12-Aug-2009	0	18-May-2010	26-May-2010	CA	WAES0908USA02397	30-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL	1	Right arm	Subcutaneously	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site reaction, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a physician concerning an 18 year old female with allergy induced asthma and allergic to sulpha who on 12-AUG-2009 was vaccinated with second dose of VARIVAX (Merck) (booster) (lot # not reported) intramuscularly. On the same day on 12-AUG-2009 she received third dose of GARDASIL (MSD) (lot #, route and site not reported). Concomitant therapy included meningococcal vaccine (unspecified) administered on 12-AUG-2009. After getting the vaccine she experienced an injection site reaction. The arm swelled up and became warm and red. The patient did not seek medical attention. At the time on the report on 12-AUG-2009 the patient was recovering. There were no laboratories diagnostics studies performed. Follow-up information was received from a physician, who reported that the female student with allergies to sulfa and AUGMENTIN received the second dose of VARIVAX (Merck) subcutaneously into right deltoid. On 12-AUG-2009, the patient developed swollen, red, 1/2 dollar size reaction and itchy. Subsequently the patient recovered. No further information is available.

Other Meds:

Lab Data: None

History:

Prex Illness: Allergic asthma; Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **388009-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Mar-2008	Unknown		19-May-2010	19-May-2010	VA		19-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Rash pruritic, Skin discolouration

Symptom Text: Diffuse pruritic rash after first vaccination. Rash slowly worsened after the next two vaccinations in series. Resulted in discoloration of skin.

Other Meds:

Lab Data: Skin biopsies

History: Atopic dermatitis

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388023-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Aug-2009	12-Aug-2009	0	18-May-2010	26-May-2010	TX	WAES0908USA02624	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0692Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypersomnia, Injection site erythema, Injection site movement impairment, Injection site warmth, No reaction on previous exposure to drug

Symptom Text: Information has been received from a medical assistant concerning a 11 year old female with no known drug reaction/allergies or pertinent medical history who on 12-AUG-2009 was subcutaneously vaccinated in the right upper arm with her second dose of VARIVAX (Merck) (lot# 664450/0692Y) and had an adverse reaction. The patient was also vaccinated with her second dose of GARDASIL on the same day. The patient did not have any reaction after the first dose of GARDASIL. Post vaccination the patient went home and became dizzy, and light headed, slept for 4 hours. The patient woke up and went to sleep again. The patient's mother took a pen and circled the injection site since it was red, stiff and warm to the touch. Since then the redness had increased outside of the pen mark at the injection site. At the time of the reporter, the patient's events persisted. The patient was being seen by the doctor for followup. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **388090-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	F	Unknown	29-Nov-2008		19-May-2010	20-May-2010	--	WAES0904USA01164B1	02-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Apgar score normal, Continuous positive airway pressure, Drug exposure during pregnancy, Intensive care, Laboratory test normal, Premature baby, Respiratory distress, Retinal disorder, Small for dates baby

Symptom Text: Information has been received from a medical assistant concerning one of twin babies. The baby's 18 year old mother was vaccinated with the first and second 0.5 ml dose of GARDASIL by different provider and was vaccinated IM with the third 0.5ml dose of GARDASIL (lot #: 659962/1740U) on 01-DEC-2008. The mother's last menstrual period was 19-NOV-2008 and estimated delivery date was 05-SEP-2009. The medical assistant reported that the baby was born about 1 month early, in approximately August 2009, but as far as she knew, the baby was born normal and healthy. Follow-up information was received from a pediatrician via medical records. It was reported that the mother delivered twin babies (one male and one female) on 13-JUL-2009. The baby girl was born on 13-JUl-2009, 32 2/7 weeks of gestation via C-section for breech position. The baby was transferred to neonatal intensive care unit (NICU) for 18 days, and on continuous positive airway pressure (CPAP) for three days. Active medications included vitamins (unspecified) (POLY-VI-SOL) 0.5 ml PO BID. On 13-AUG-2009, the baby's weight was 5 pounds, 15 ounces, length was 18.5 inch, and head circumference was 13 inch. Her body temperature was 98, pulse was 136, and respiratory rate was 40. Physical examination showed the baby was alert, premature and active. The assessment was the female baby was one month old, premature, was doing well, and breech of birth. The baby continued diet Neosure 22 kcal/ounce and vitamins (unspecified) (POLY-VI-SOL). An ultrasound for hips was scheduled. Barlow and Ortolani tests were negative. The baby would be arranged "for syringes, monthly injection". On 04-SEP-2009, the baby had hip click alignment check. Ultrasound infant hips with physician guided was performed which showed both hips were within normal limits. The mother's experience has been captured in WAES # 0904USA01164. The twin baby's experience has been captured in WAES # 0904USA01164B2. Additional information has been requested. All available medical records will be provided upon r

Other Meds: betamethasone; loratadine

Lab Data: Ultrasound, 09/04/09, hip click alignment check: both hips were within normal limits ```Labs and DX studies: CXR normal with no abnormality. U/S of head normal.

History: Unknown ```PMH: twin gestation, maternal use of steroids, maternal exposure to vaccination during pregnancy, premature rupture of membranes, breach presentation, teen pregnancy (mother), maternal PIH. Allergies: none.

Prex Illness:

Prex Vax Illns: Drug exposure during~HPV (Gardasil)~2~0.00~Sibling|Neonatal respiratory; Premature baby 33 to 36; Retinal disorder~HPV (Gardasil)~3~0.00~Sibling

Vaers Id: **388135-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-May-2010	27-May-2010	PA	WAES0904USA01426	30-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Rash

Symptom Text: Information has been received from a nurse concerning a female who on unspecified date was vaccinated with a of VARIVAX (Merck) 0.5ml (route and lot number was not provided) and GARDASIL (Merck) on the same day. The nurse reported "one day after vaccination" the patient experienced a 103 fever and a localized rash on the arm the VARIVAX (Merck) was given. The patient's outcome was reported as recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **388173-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Feb-2010	17-Apr-2010	60	19-May-2010	20-May-2010	FL	HumanPapillomavirusQuadri	20-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Balance disorder, Confusional state, Disturbance in attention, Feeling abnormal, Hypoaesthesia

Symptom Text: Loss of balance, numbness in arms and legs. Brain fog, inability to concentrate, feeling like being in a movie, very confused. Episode lasted one week. Saw primary doctor as well as shrink. Anti-anxiety drugs were prescribed but did not help. Multiple similar episodes occuring. Patient unable to complete school year.

Other Meds:

Lab Data: MRI, EEG, blood work - all normal

History: None

Prex Illness: pain at injection site

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388184-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
56.0	F	19-May-2010	19-May-2010	0	19-May-2010	20-May-2010	MA	MA	20-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Paraesthesia oral, Pharyngeal oedema, Similar reaction on previous exposure to drug, Swollen tongue

Symptom Text: I experienced in my mouth tingling of my tongue, lips and mouth. Tongue felt swollen as well as the back of my throat. Ended up in Emergency Room hospital for 5 1/2 hours. Received Epi-pen, Solumedrol 60 mg po, Zantac 50 mg IV. Observed until 8:00 pm. Discharged with Epi-pen and took another Zantac 150 mg po. Some symptoms returned, but mild. I also had a similar reaction to Benadryl IV back on March 25, 2010. I am wondering if this is being caused by the preservative in these drugs.

Other Meds:

Lab Data:

History: Allergic to Benadryl IV, Cipro, Demerol, latex

Prex Illness: no

Prex Vax Illns:

Vaers Id: **388208-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Aug-2008	Unknown		18-May-2010	27-May-2010	ND	WAES0811USA03020	04-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B027AA		Unknown	Unknown	
FLU	UNKNOWN MANUFACTURER	U2828AA		Unknown	Unknown	
HPV4	MERCK & CO. INC.	1967U		Unknown	Unknown	
MNQ	SANOFI PASTEUR	U2665AA		Unknown	Unknown	
VARCEL	MERCK & CO. INC.	0329X		Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Assisted delivery, Complication of pregnancy, No adverse event, Pregnancy induced hypertension, Prolonged labour, Weight increased

Symptom Text: Initial and follow-up information had been received from a physician for the Pregnant Registry for VARIVAX (Merck) concerning a 16 year old female patient with a history of 0 pregnancies and 0 live births who on 08-AUG-2008 was vaccinated subcutaneoulsy with a 0.5ml dose of VARIVAX (Merck) (Lot # 659953/0329X) on the same day the patient was vaccinated with a dose of GARDASIL (lot # 660387/1967U). Concomitant therapy included prenatal vitamins (unspecified), INFANRIX (lot #AC52B027AA), MENACTRA (lot # U2665AA), influenza virus vaccine (unspecified) (lot # U2828AA), and TYLENOL. Subsequently, the patient became pregnant (LMP 27-JUL-2008 and EDD 03-MAY-2009), and on 04-MAY-2009, delivered a normal, healthy male baby weighing 38.95 grams. There were complications during the pregnancy as excessive weight, gestational hypertension and protracted labor required vacuum assist. It was reported that pre-natal blood work had normal results, a pre-natal ultrasound on 30-DEC-2008 showed no abnormalities, and a serum alpha-fetoprotein test (MSAFP) on 04-FEB-2008 was normal. No adverse effects reported. Additional information is not expected.

Other Meds: TYLENOL; vitamins (unspecified)

Lab Data: diagnostic laboratory, pre-natal blood work, results normal; ultrasound, 12/30/08, normal; serum alpha-fetoprotein, 02/04/09, normal

History:

Prex Illness: Pregnancy NOS (LMP = 7/27/2008); Headache

Prex Vax Illns:

Vaers Id: 388382-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-May-2008	21-May-2008	0	20-May-2010	21-May-2010	FR	WAES1005USA01156	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0900U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Fatigue, Gait disturbance, Headache, Menstruation delayed, Muscular weakness, Nausea, Vaccine positive rechallenge, Walking aid user

Symptom Text: Information was obtained on a request by the Company from the agency via a Public Case Detail form concerning a 14 year old female patient with no psychiatric history and no family history of MS (multiple sclerosis) who was vaccinated with three doses of GARDASIL, started on 21-MAY-2008 (lot# 658278/0900U) and stopped on 15-OCT-2008. Subsequently the patient experienced stomach pain after each vaccine. On 21-MAY-2008 the patient experienced constant nausea, severe headaches and chronic fatigues. In November 2009 the patient lost use of her legs, she was using a walking stick. The patient had not been to school for a year and at the time of the report she was only taking a couple of classes per week. On an unknown date the patient was hospitalized. She was treated with VOLTAREN. At the time of the report, symptoms persisted. It was reported that menstruations halted not to return until February 2009 (not specified). Blood test, CT scans, X-rays and laparoscopy were performed, with no abnormality detected (NAD). The agency considered that abdominal upper pain, fatigue, headache, muscular weakness and nausea were possibly related to vaccination with GARDASIL. The original reporting source was not provided. No further information is available.

Other Meds: Unknown

Lab Data: Computed axial tomography, NAD (No Abnormality Detected); X-ray, NAD (No Abnormality Detected); Laparoscopy, NAD (No Abnormality Detected); Hematology, blood test: NAD (No Abnormality Detected)

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 388384-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-May-2007	01-Nov-2007	168	20-May-2010	21-May-2010	NH	WAES1005USA01462	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Cough, Fatigue, Hypersomnia, Hypoaesthesia, Increased tendency to bruise, Migraine, Muscular weakness, Musculoskeletal stiffness, Myalgia, Nasal congestion, Nausea, Neurological examination normal, Oropharyngeal pain, Paralysis, Pyrexia, Tremor, Upper respiratory tract infection, Vision blurred, Vomiting

Symptom Text: Information has been received from a female consumer concerning her 12 year old daughter with allergic reaction to antibiotics (amoxicillin) and no pertinent medical history reported who received the first dose of GARDASIL vaccine "3 years ago", in approximately April 2007. It was reported that the patient had all three doses of GARDASIL vaccine (dates not specified). According to the reporter "2 and a half years ago", on approximately November 2007, the patient experienced temporary paralysis from the waist down, migraines for three months straight that progressively got worse. She was tired all the time and went from an active person to someone who could barely get out of bed. The patient also bruised easily, was shaky, sometimes had no feeling in her arms and legs and had high fevers. The consumer stated that the doctors said that "it was all in the patient's head". The patient was going to see a neurologist, possibly in July 2010. The patient sought unspecified medical attention. At the time of the report the patient had not recovered. No diagnostic tests were performed. Upon internal review temporary paralysis from the waist down was determined to be another important medical event. The health care professional contacted during telephone follow-up could not supply the following information: dates of vaccination, lot numbers, dates of events. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 5/27 and 5/28/2010 MR for PCP ovs 4/15/2009-5/19/2010, Dx Chronic fatigue, Migraines, URI patient with c/o's arthralgias, myalgias. am stiffness, fatigue, exhaustion, unable to perform at school ,hypersomnolence, had a complete rheumatology w/up, lab studies were negative, but sx continued, somatic c/o's thought to be due to anxiety/depression, placed on Zoloft, then developed severe headaches with nausea/vomiting, blurred vision, weakness LLE, neuro exam wnl, dx'd as migraines, also c/o's sore throat, nasal congestion, cough and fever

Other Meds: Unknown

Lab Data: None The following information was obtained through follow-up and/or provided by the government. 5/27 and 5/28/2010 MR for PCP ovs 4/15/2009-5/19/2010, Dx Chronic fatigue, Migraines, URI Labs: monospot, CMV, CPK, Hep C, CBC, CMP all wnl D

History: The following information was obtained through follow-up and/or provided by the government. 5/27 and 5/28/2010 MR for PCP ovs 4/15/2009-5/19/2010, Dx Chronic fatigue, Migraines, URI PMH: acne, GERD Allergies: Amoxicillin

Prex Illness: Allergic reaction to antibiotics The following information was obtained through follow-up and/or provided by the government. 5/2

Prex Vax Illns:

Vaers Id: **388389-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Jul-2009	30-Jul-2009	6	20-May-2010	21-May-2010	FR	WAES1005USA02096	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1864U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bacterial infection, Nasopharyngitis, Peritonsillitis, Pyrexia, Tonsillitis, Vaccine positive rechallenge

Symptom Text: Information has been received from a Health Authority (HA ref. 101689) concerning a 14-year-old girl who was vaccinated with GARDASIL (unknown route, 0.5 ml) on 24-JUL-2009 (first dose, batch number NJ11570, lot # 1864U, on 18-SEP-2009 (second dose, batch number NK02480, lot # 0719X) and on 26-MAR-2010 (third dose, batch number NL30760, lot# 1334X). HA reported all three doses as suspected and positive rechallenge. HA coded bacterial infection (causality possible) with first time onset on 30-JUL-2009, six days following vaccination with the first dose. Stated in the report: "Previously health girl who following vaccination with GARDASIL developed symptoms of infection, peritonsillitis and tonsillitis." On 30-JUL-2009, six days post following administration of the first dose, the girl developed peritonsillitis and received treatment at the hospital (no details reported). On 22-SEP-2009, four days following vaccination with the second dose, the girl developed tonsillitis. On 31-MAR-2010, five days after vaccination with the third dose, the girl experienced common cold and fever. The outcome was recovered without sequale. No further information was available at the time of reporting. Case is closed. Other business partner numbers include E2010-03043.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388402-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	M	19-May-2010	19-May-2010	0	20-May-2010	20-May-2010	TX		27-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1670Y	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1316Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainting episode 2 hours HPV.

Other Meds:

Lab Data:

History: No

Prex Illness: Well visit

Prex Vax Illns:

Vaers Id: **388418-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	18-May-2010	19-May-2010	1	20-May-2010	20-May-2010	KS		26-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Decreased appetite, Feeling cold, Headache, Injection site erythema, Injection site pain, Injection site swelling, Pyrexia, Skin warm, Somnolence

Symptom Text: 5/19/10 - Fever/chills, not eating, sleepy, pain at site of injection, 1/4 size swelling, redness, headache. Body is warm from head to abdomen and cold from knees to toes. Inner thighs warm, outer thighs cold.

Other Meds:

Lab Data:

History:

Prex Illness: Takes seizure medication TID

Prex Vax Illns:

Vaers Id: **388480-1 (S)** **Related reports:** 388480-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Dec-2009	05-Feb-2010	38	20-May-2010	21-May-2010	TX		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0968Y	1	Right arm	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain upper, Chest pain, Dyspnoea, Electrocardiogram T wave inversion, Fatigue, Infectious mononucleosis, Influenza like illness, Menorrhagia, Nausea, Palpitations, Pericarditis, Vomiting

Symptom Text: Patient received dose #1 GARDASIL on 10/29/9 - mother stated pt had flu-like s/s for 2 days post injection, did not report such to our office until after 2nd immuz. On 12/29/2009 received 2nd GARDASIL injection (diagnosed with mononucleosis on 12/4/2009), developed CP, SOB, nausea, vomiting on 2/5/10. Seen by Dr (cardiologist) dx with pericarditis, placed on ibuprofen 800 mg PO TID and taken out of sports, spoke to mother on 2/10/10 - Patient better, mother convinced recurrent s/s related to adverse effect from #2 GARDASIL. The following information was obtained through follow-up and/or provided by the government. 06/01/09. PCP notes for 12/04/09, 02/05/10. Pt c/o of continuing stomach aches, fatigue, SOB, nausea, vomiting, chest pain. DX mononucleosis. 06/09/10. Cardiology consult for DOS 02/01/10. Pt c/o chest pain, dyspnea and palpitations. Pt reported R parasternal cheskt pain with no radiation. EKG findings suggested pericarditis, nonspecific T wave inversion. Tx: Ibuprofen. Echocardiogram confirmed acute idiopathic pericarditis. Assessment: chest pain, dyspnea, palpitations, probable pleural pericarditis. F/U visit on 02/05/10, Pt c/o dyspnea, some chest pain. Assessment: pericarditis. On 02/25/10, Pt's symptoms had resolved, but Pt had menorrhagia.

Other Meds: YAZ; DORYX; DIFFERIN; BENZACLIN

Lab Data: None in our office The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: ECG and Echocardiogram abnormal. BNP normal. Mono test positive.

History: NKDA The following information was obtained through follow-up and/or provided by the government. PMH: URI, SOB, estrogen tx for menorrhagia, appendectomy in 2007. Allergies none.

Prex Illness: Mononucleosis - recovering

Prex Vax Illns:

Vaers Id: **388480-2 (S)** **Related reports:** 388480-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Oct-2009	29-Oct-2009	0	06-Jul-2010	07-Jul-2010	--	WAES1006USA02892	07-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Activities of daily living impaired, Chest pain, Condition aggravated, Dyspnoea, Infectious mononucleosis, Influenza like illness, Nausea, Pericarditis, Vomiting

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 15 year old female patient with no known drug allergies was vaccinated with the first dose of GARDASIL on 29-OCT-2009. Concomitant medications included YAZ, DORYX, DIFFERIN and BENZACLIN. The patient's mother reported that the patient had flu-like signs/symptoms for 2 days post injection, it was not reported to the physician's office until after the second dose of GARDASIL (Lot # 661758/0968Y) was administered on 29-DEC-2009, into the patient's right arm. On 04-DEC-2009, the patient was diagnosed with mononucleosis, the patient developed CP (chest pain), SOB (shortness of breath), nausea and vomiting on 25-FEB-2010. The patient was seen by a doctor (cardiologist) with a diagnosis of pericarditis, she was placed on therapy with ibuprofen 800 mg, PO TID and was taken out of sports. The office spoke to the mother on 10-FEB-2010 and the patient was doing better, the mother was convinced that the recurrent signs/symptoms were related to adverse effects from the second dose of GARDASIL. No laboratory data was available in the office. The original reporting source was not provided. The VAERS ID # 388480. The listing indicated that one or more of the events was considered to be immediately life-threatening. A lot check has been initiated. A standard lot check investigation has been finalized. All in-process quality checks for the lot number 661758/0968Y were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center for Biologics Evaluation and Research and was released. No further information is available.

Other Meds: DIFFERIN; BENZACLIN; DORYX; YAZ

Lab Data: Unknown

History: Infectious mononucleosis

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388486-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Jan-2010	Unknown		20-May-2010	21-May-2010	NJ		21-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Epstein-Barr virus antibody positive, Lymphadenopathy, Skin papilloma

Symptom Text: After 3rd Gardasil shot had swollen lymph under arm then got a planters wart on foot had it removed then both lymph nodes in throat swelled took blood work many times showing lymphs high and then found Epstein Barr after 4th bloodwork.

Other Meds: There were no other vaccines at the time of last Gardasil shot

Lab Data: Bloodwork - 4

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388497-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	05-Nov-2009	10-Nov-2009	5	20-May-2010	21-May-2010	CA		21-May-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3047AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0249Y	0	Right arm	Intramuscular	
FLUN	MEDIMMUNE VACCINES, INC.	500693P	0	Unknown	Unknown	
TDAP	SANOFI PASTEUR	C3250AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bronchospasm, Chest discomfort, Dizziness exertional, Dyspnoea, Exercise tolerance decreased, Fatigue, Pruritus, Rash generalised, Rash macular, Rash papular, Urticaria

Symptom Text: On 11/5/09 received HPV#1, MCV4, Tdap, FluMist. On 11/10/09 experienced hard time catching breath, chest tightness, and dizziness while doing a long distance run. Dx with bronchspasm on 11/16/09. Given Proventil inhaler for excercise induced bronchospasm. Continued to complain of fatigue and reduced endurance during endurance sport activities. Got HPV#2 on 1/7/10 with no problems. Got HPV#3 5/6/10. On 5/17/10 at 10:00AM experienced itchy, full body rash which was red blotchy raised with small welts. Took Benadryl the rest of the day and night. The next morning at 7:00 the rach was mostly gone. Continues to be fatigued.

Other Meds: No routine medications. Given Proventil inhaler for broncho spasms. Took OTC Benadryl for rash. HPV#2 Merck Lot 0930U admin 1/7/10. HPV#3 Merck Lot 1099Y admin 5/6/10

Lab Data:

History: Denies Any

Prex Illness: Denies Any

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388647-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-May-2010	05-May-2010	2	21-May-2010	21-May-2010	MO	MO201010	21-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3353AA	5	Right arm	Unknown	
	HEPA	MERCK & CO. INC.	1670Y		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1378Y		Right arm	Unknown	
	MEN	SANOFI PASTEUR	U3078AA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site nodule, Injection site pain

Symptom Text: Received Tdap on 5/3/10. On 5/5/10 site began to get red (size of baseball) and knot under injection site size of a quarter. Pain when touching site.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **388798-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		21-May-2010	24-May-2010	FR	WAES1005USA02429	24-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Vaccination complication

Symptom Text: An online magazine reported according to a school principal and a physician that a girl who on an unknown date was vaccinated with a dose of GARDASIL suffered from complication and was admitted to the hospital. A physician from the hospital said that anxiety, heat and empty stomachs caused the complications. The physician stated, referring to other girls who experienced symptoms with GARDASIL, that "all the girls, who had complications, did not take breakfast and do not bring lunch". But teachers said that, since health officials and teachers had created awareness with students and parents about the vaccine, the girls would not have come to school on empty stomachs. A teacher stated that "it's also compulsory for all students to bring lunch". At the time of the report, the outcome of the patient was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: unknown

Lab Data: unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388801-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	23-Jan-2009	11-May-2009	108	21-May-2010	24-May-2010	KY	WAES0907USA01322	26-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner for GARDASIL, a Pregnancy Registry product, concerning a 24 years old female with no drug allergies and no pertinent medical history who on 06-NOV-2008 was vaccinated with the first dose of GARDASIL (lot number unknown). On 23-JAN-2009 the patient was vaccinated with the second dose of GARDASIL (lot number 661703/0651X). On 12-JUN-2009 the patient was vaccinated with the third dose of GARDASIL (lot number 661703/0651X). The patient became pregnant around the time of the 3rd dose GARDASIL. Pregnancy is normal to date. The patient's LMP was reported as 24-MAY-2009. The estimated delivered date would be on 28-FEB-2010. Follow-up information was received from the consumer via a completed outcome pregnancy questionnaire. It was reported that the patient did not have any previous pregnancies, pre-term deliveries, spontaneous abortions, elective terminations or fetal deaths. The estimated conception date was 11-MAY-2009. On 16-FEB-2010, the patient delivered a normal female baby with no congenital anomalies weighing 8 pounds, 7 ounces, length 20 inches. The patient had no complication and no infections or illnesses during pregnancy. It was reported that the baby was stuck, so the patient had to have a C-section. The patient had no concurrent medical conditions. Upon internal review, C-Section was determined to be an other important medical event. Subsequently, the baby experienced heart murmur. The baby's experience was captured in WAES#0907USA01322B1. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, confirmed pregnancy

History:

Prex Illness: Pregnancy NOS (LMP = 5/24/2009)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388834-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2010	01-May-2010	0	21-May-2010	24-May-2010	FR	WAES1005USA02508	24-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia

Symptom Text: An online magazine reported according to a school principal that a girl a history of chronic malaria and dysentery who on 05-MAY-2010 was vaccinated with a dose of GARDASIL and was admitted to the hospital complaining of giddiness, headache and numbness. A physician from the hospital said that anxiety, heat and empty stomachs caused the complications. The physician stated, referring to other girls who experienced symptoms with GARDASIL, that "all the girls, who had complications, did not take breakfast and do not bring lunch". But teachers said that, since health officials and teachers had created awareness with students and parents about the vaccine, the girls would not have come to school on empty stomachs. A teacher stated that "it's also compulsory for all students to bring lunch". It was reported that patient had been discharged and at the time of this report the outcome of the patient was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Malaria; Dysentery

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388835-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	05-May-2010	Unknown		21-May-2010	24-May-2010	FR	WAES1005USA02507	24-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia

Symptom Text: An online magazine reported according to a school principal that a girl a history of chronic malaria and dysentery who on 05-MAY-2010 was vaccinated with a dose of GARDASIL and was admitted to the hospital complaining of giddiness, headache and numbness. A physician from the hospital said that anxiety, heat and empty stomachs caused the complications. The physician stated, referring to other girls who experienced symptoms with GARDASIL, that "all the girls, who had complications, did not take breakfast and do not bring lunch". But teachers said that, since health officials and teachers had created awareness with students and parents about the vaccine, the girls would not have come to school on empty stomachs. A teacher stated that "it's also compulsory for all students to bring lunch". It was reported that patient had been discharged and at the time of this report the outcome of the patient was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Malaria; Dysentery

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388837-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	05-May-2010	Unknown		21-May-2010	24-May-2010	FR	WAES1005USA02503	24-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia

Symptom Text: An online magazine reported according to a school principal that a girl a history of chronic malaria and dysentery who on 05-MAY-2010 was vaccinated with a dose of GARDASIL and was admitted to the hospital complaining of giddiness, headache and numbness. A physician from the hospital said that anxiety, heat and empty stomachs caused the complications. The physician stated, referring to other girls who experienced symptoms with GARDASIL, that "all the girls, who had complications, did not take breakfast and do not bring lunch". But teachers said that, since health officials and teachers had created awareness with students and parents about the vaccine, the girls would not have come to school on empty stomachs. A teacher stated that "it's also compulsory for all students to bring lunch". It was reported that patient had been discharged and at the time of this report the outcome of the patient was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Malaria; Dysentery

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388838-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	05-May-2010	Unknown		21-May-2010	24-May-2010	FR	WAES1005USA02502	24-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia

Symptom Text: An online magazine reported according to a school principal that a girl who on 05-MAY-2010 was vaccinated with a dose of GARDASIL was admitted to the hospital complaining of giddiness, headache and numbness. A physician from the hospital said that anxiety, heat and empty stomachs caused the complications. The physician stated, referring to other girls who experienced symptoms with GARDASIL, that "all the girls, who had complications, did not take breakfast and do not bring lunch". But teachers said that, since health officials and teachers had created awareness with students and parents about the vaccine, the girls would not have come to school on empty stomachs. A teacher stated that "it's also compulsory for all students to bring lunch". It was reported that patient had been discharged and at the time of this report the outcome of the patient was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388840-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	05-May-2010	Unknown		21-May-2010	24-May-2010	FR	WAES1005USA02501	24-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia

Symptom Text: An online magazine reported according to a school principal that a girl who on 05-MAY-2010 was vaccinated with a dose of GARDASIL was admitted to the hospital complaining of giddiness, headache and numbness. A physician from the hospital said that anxiety, heat and empty stomachs caused the complications. The physician stated, referring to other girls who experienced symptoms with GARDASIL, that "all the girls, who had complications, did not take breakfast and do not bring lunch". But teachers said that, since health officials and teachers had created awareness with students and parents about the vaccine, the girls would not have come to school on empty stomachs. A teacher stated that 'it's also compulsory for all students to bring lunch". It was reported that patient had been discharged and at the time of this report the outcome of the patient was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388841-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	05-May-2010	Unknown		21-May-2010	24-May-2010	FR	WAES1005USA02499	24-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia

Symptom Text: An online magazine reported according to a school principal that a girl who on 05-MAY-2010 was vaccinated with a dose of GARDASIL was admitted to the hospital complaining of giddiness, headache and numbness. A physician from the hospital said that anxiety, heat and empty stomachs caused the complications. The physician stated, referring to other girls who experienced symptoms with GARDASIL, that "all the girls, who had complications, did not take breakfast and do not bring lunch". But teachers said that, since health officials and teachers had created awareness with students and parents about the vaccine, the girls would not have come to school on empty stomachs. A teacher stated that "it's also compulsory for all students to bring lunch". It was reported that patient had been discharged and at the time of this report the outcome of the patient was unknown. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388853-1** **Related reports:** 388853-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Apr-2010	Unknown		21-May-2010	21-May-2010	IL		11-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Patient received 1st dose of GARDASIL while pregnant. VFC questionnaire completed but as per pt's mother and older sister pt. did lie & withhold information. Pt instructed to follow up with OB clinic ASAP. This is in follow-up to report(s) previously submitted on 05/21/2010. No adverse reactions noted as of 6/9/10 clinic just wanted to notify CDC of incident.

Other Meds:

Lab Data: Positive urine HCG

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388853-2** **Related reports:** 388853-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Apr-2010	15-Mar-2010	-44	18-Jun-2010	21-Jun-2010	--	WAES1005USA03042	21-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure before pregnancy

Symptom Text: Information has been received from a registered nurse, for the pregnancy registry for GARDASIL, concerning a 15 year old female patient who on 28-APR-2010 was vaccinated with the first dose of GARDASIL (dose and route not reported; lot number 663573/0969Y). Nurse reported that the patient became pregnant after receiving GARDASIL approximately 15-MAR-2010 and she had 9 weeks of gestation at the time of the report (EDD: 20-DEC-2010 approx.). Therapy with the vaccine was discontinued and it was not reintroduced. The patient sought unspecified medical attention. Follow up information has been received from the health care provider who reported that the 15 year old female on 27-MAY-2010 had an elective termination of her pregnancy. The patient does not want to participate in the pregnancy registry for GARDASIL. Upon internal review, abortion was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 3/15/2010)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **388940-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-May-2010	20-May-2010	1	21-May-2010	24-May-2010	MN		25-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	U2937BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3014AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain, Injection site reaction, Injection site swelling, Injection site warmth

Symptom Text: Swollen, warm local reactions of the injection site. Tdap tender indurated 100mm x 100mm redness 60 mm x 80mm tender. HPV site with tenderness extending 70mm x 40mm from injection site and redness 25mm x 25mm. MENACTRA site area of tenderness 30mm size.

Other Meds: None

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **389011-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	02-Jul-2008	03-Jul-2008	1	21-May-2010	24-May-2010	ND		24-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Dizziness, Dyspnoea, Fatigue, Feeling abnormal, Hypoaesthesia, Insomnia, Memory impairment, Migraine, Muscle spasms, Muscle twitching, Muscular weakness, Night sweats, Pain, Paraesthesia

Symptom Text: Symptoms: severe generalized pain, dizziness, muscle weakness, muscle spasms, numbness, migraines, memory problems, brain fog, insomnia, shortness of breath, tingling, muscle twitching, fatigue, muscle cramping, night sweats, shivering when not cold, etc. Treatment: chiropractic adjustments 1-3 times a week, regular MD visits, rheumatologist visit, neurologist visit, second rheumatologist visit scheduled, etc.

Other Meds: none

Lab Data: ANA, CRP, sed rate, BMP, electrolytes, blood glucose, kidney fuction tests, etc.

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **389120-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Jul-2009	14-Jul-2009	6	24-May-2010	25-May-2010	SC	WAES1005USA01579	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1131X	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2907BA		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Laboratory test normal, Neck pain, Tenderness

Symptom Text: Information has been received from a physician concerning a 16 year old female with acne, migraine, dysmenorrhea, mid cycle pain and oxycodone allergy (it was for a broken bone sustained in an athletic incident, much prior to receiving GARDASIL) who on 08-JUL-2009 was vaccinated IM with the first dose of GARDASIL (lot# 661954/1131X). Concomitant therapy included MENACTRA and minocycline. On 14-JUL-2009 the patient began to complain of neck pain and joint pain. Neck pain and joint pain happened twice in the week following the vaccination. On 17-JUL-2009, she went to her pediatrician, who noted that there was no joint swelling, redness, nor heat. On 10-AUG-2009, she went to a pediatric rheumatologist, who stopped the minocycline (for acne), and gave an anti-inflammatory for the neck pain and joint pain. Lab and diagnostic studies were normal. She recovered during the winter of 2009 (approximately December 2009). Neck pain and joint pain were considered to be other important medical events by the rheumatologist. Neck pain and joint pain were considered to be disabling since the patient couldn't go to school. No further information is available. The following information was obtained through follow-up and/or provided by the government. 05/28/10. PCP notes for DOS 07/08/09. DX Pt for well visit. On 07/17/09, Pt c/o neck pain, joint pain. On exam neck was painful, but not stiff. Impression: arthralgia (etiology uncertain). Tx: antiinflammatories. 06/03/10. Rheumatology visit for 08/10/09. Pt c/o HA and neck pain. On exam: Pt had pain on flexion and extension and tenderness in neck, shoulders, BLE and ULE. Assessment: polyarthria likely due to minocycline. Pt stopped minocycline and started Relafen.

Other Meds: Minocycline

Lab Data: Unknown

History: Broken bones; Accident The following information was obtained through follow-up and/or provided by the government. PMH: dysmenorrhea, midcycle pain, migraine HA, viral meningitis. Allergies: Oxycodone.

Prex Illness: Acne; Migraine; Dysmenorrhoea; Mid cycle pain; Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389128-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Jun-2008	Unknown		24-May-2010	24-May-2010	NM		01-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	71267U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Electroencephalogram abnormal, Syncope

Symptom Text: I saw patient on 5/06/09 - Thin with history of fainting spells, near "black outs" that started summer '08. Start near time of 2nd HPV. Symptoms worsen from 3/09-5/6/09. Multiple labs, EKG, cardiology eval was done. EEG 8/4/09 was abnormal. Placed on Keppra 750 mg BID. Followed by neurology. Follow up - Please note - the exact "onset date" can not be determined. You may wish to contact the mother of patient for more details; she stated that she was available for questions. Pt received her first HPV on April 15, 2008, along with Tdap, MCV4, and Hep A. On June 17, 2008, pt mentioned that she had almost fainted the previous week, and that she had been having episodes of "near-fainting" approximately once per week since her second HPV. She stated at that time that she never falls to the floor but feels that if she does not hold herself, she would probably fall. No exact date as to when first episode occurred except to say that it started around the time of the second HPV. I told mom to keep calendar of these near-fainting episodes (I felt at that time that the patient's diet was a possible cause). Pt received her third HPV that day. On October 29, 2008, I saw pt for a sport physical. Mom felt that the near-fainting episodes were better and may have resolved. She did mention that after the third HPV, that her daughter was a "little fainty". On May 06, 2009, pt came in because for the last 2 months the near-fainting spells were now daily. Mom stated that in the fall of 2008, near-fainting episodes were few and far between but now were almost daily. labaoratory workup and EKG were done. She was referred to a cardiologist, and to a neurologist. Pt saw a neurologist on July 10, 2010, and attributed her near-syncopal episodes to dehydration. On August 04, 2009, pt had an abnormal EEG. As a result of the abnormal EEG, pt was started on KEPPRA, an anticonvulsant. On follow-up visit witht the neurologist on October 22, 2009, her near-syncopal episodes resolved with KEPPRA. Patient's last name corrected.

Other Meds: Albuterol MDI for Asthma

Lab Data: Abnormal EEG on 08/04/2009.

History: Mild intermittent asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: **389134-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Mar-2010	Unknown		24-May-2010	24-May-2010	AL		02-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Swelling

Symptom Text: Patient stated her hold right side was swollen. Patient came in for 3rd dose and told the doctor what happen on 3/12/2010.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **389154-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-May-2010	20-May-2010	0	24-May-2010	24-May-2010	TX		04-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	2	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF486DA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bruxism, Crying, Cyanosis, Feeling abnormal, Musculoskeletal stiffness, Unresponsive to stimuli, Urinary incontinence

Symptom Text: Approximately 5 minutes after immuns given, nurse called to waiting room because receptionist thought she heard pt "crying". Pt in chair unresponsive, LE extended, arms and hands clenched into body, back arched over side of chair, mouth clenched, sl. circumoral cyanosis. Pt started to arouse as soon as attempt was made to reposition pt. Dazed but knew she was in the Dr's office. Also noticed pt had been incontinent of urine. By 1630-1635 < pt alert, responsive, oriented, lying down with feet up. DC'ed home with father about 1715.

Other Meds: None

Lab Data: No labs or test at present. Referred to Neuro for evaluation and to Cardiology for EKG only

History: Pt reported she passed out with IV when she had ankle surgery 2/09 & that for thought she had AST at that time - Reported after above episode

Prex Illness: None

Prex Vax Illns:

Vaers Id: **389174-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Apr-2010	15-Apr-2010	0	24-May-2010	25-May-2010	IN		01-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1321Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1178Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Anaemia, Dizziness, Loss of consciousness, Urinary incontinence

Symptom Text: Pt was given 2 shots on 4/15/10. One was varicella and one was HPV. Immediately after vaccination the pt got lightheaded so we sat her on the floor with head down and feet up until she felt better. She returned back to class that day. The next day (4/16/10) as she was in the lunch line at school her stomach began to hurt and she got dizzy. She went to tell her line teacher. As she got to her and began to tell her she wasn't feeling good she went down and the teacher caught her. She doesn't remember after that. She passed out and peed her pants. Her grandmother and mother were called in and she was taken to the Dr. where lab work was ordered. The found that she was anemic. All lab results will be with VAERS form. Description of incident per RN administrator of vaccine and per pt mother per phone call.

Other Meds:

Lab Data: CBC; EEG

History: After this lab shown anemia

Prex Illness: None known previous

Prex Vax Illns: light headed~HPV (no brand name)~1~12.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389191-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-May-2010	20-May-2010	0	24-May-2010	25-May-2010	FL		25-May-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB362BA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1498Y	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3046AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0025Z	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Carpal tunnel syndrome, Pain in extremity

Symptom Text: Right wrist pain that resolved. On Sunday started to have left wrist pain. Got worse. Family called said having pain in arm due to shots. Diagnosis carpal tunnel syndrome. Patient finish large project for school and was typing a lot.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389213-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Mar-2010	01-Apr-2010	9	25-May-2010	26-May-2010	TX		04-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Diarrhoea, Dizziness, Dyspnoea, Fatigue, Hyperhidrosis, Joint swelling, Lip swelling, Pain in extremity, Rash erythematous, Urticaria, Vomiting, Wheezing

Symptom Text: Severe rash - all over (legs, arms, feet, hands, lots of rash -spots (red), swelling in hands & fingers, toe (joint swelled), lips swelled, wheezing, shortness of breath, vomited, fatigue, diarrhea, stomach pain legs ached, joint pain. Sweaty, dizzy, hives. Doctor gave PREDNISONE/METHYLPREDNISOLONE (several times).

Other Meds: none

Lab Data: High WBC (double what it was for last check-up)

History: none

Prex Illness: none-felt great

Prex Vax Illns:

Vaers Id: **389223-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Feb-2010	Unknown		25-May-2010	26-May-2010	IN		15-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Fatigue, Haematochezia, Headache, Hypoaesthesia, Myalgia, Pain in extremity

Symptom Text: Numbness in toes, then pelvic area and upper extremities. Muscle soreness in arms, legs, chest wall. Headaches. Fatigue. Blood in stool for 2 days. Symptoms have not lessened, and additional symptoms developing with time.

Other Meds: PATADAY; FLONASE

Lab Data: CBC; CMP; ESR; TSH; B12; monospot; 24 hour urine heavy metals - all neg. MRI brain + spine - (R) posterior frontal venous angioma and sinusitis; L5-S1 retrolisthesis; EMG/NCS-BLE normal; ANA 1:160

History: Nickel; rash with Aluminum in deodorants

Prex Illness: Sore throat x 2 weeks; giant papillary eyelid infection

Prex Vax Illns:

Vaers Id: **389278-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Jul-2008	Unknown		25-May-2010	26-May-2010	MO	WAES1005USA02000	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Deja vu, Epilepsy, Gaze palsy, Grand mal convulsion, Insomnia, Mood disorder due to a general medical condition, Nasopharyngitis, Rash, Road traffic accident, Skin laceration

Symptom Text: Information has been received from a physician and a licensed practical nurse concerning an approximately 20 year old "college age" female with seizure disorder and no known allergies who was vaccinated with all three doses of GARDASIL on 07-AUG-2007, 02-NOV-2007, and 24-JUL-2008 (1st lot # 657622/0388U, 2nd lot #658563/1063U, 3rd lot #660555/0279X), respectively. On 10-MAY-2010, after hearing reports in the media, the patient contacted her physician's office to report that she had more seizures. She had four seizures since her last dose of GARDASIL (no dates given for seizures). The patient was being seen by a neurologist. At the time of the report, the outcome was unknown. The health care professional contacted during telephone follow-up could not supply the following information: date of event, recovery status. Upon internal review, more seizures was considered to be an other important medical event. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 6/1/10 Mr received for date 3/9/09. DX: viral erythema vs CC: rash x2 days, cold x2 wks. Pt playing with body paint prior to rash. 6/4/10 MR received for date 7/27/07 neuro consult. DX: seizures CC; pt free from seizure activity for several years. Pt on anti seizure medication. OV 1/23/09 neuro f/u pt had seizure after sleep deprivation. This was pt first seizure in 3 years. MD discussed importance of rest. OV 7/2/09 Neuro f/u. Pt had seizure several days ago. Pt states had viral infection, fever, sinus congestion at that time. Office notes on 1/28/10 state pt had seizure while driving. Medication levels WNL. OV 3/2/10 and 4/23/10 noted pt had another seizure. 6/4/10 Neurology consultations received for dates of service 7/27/07 to 4/23/10. Dx: Epilepsy, generalized tonic clonic seizures. 7/27/07 Pt. doing well, remains seizure free. 5/7/08 Had a seizure while on spring break with irregular food and sleep hours. 1/23/09-Pt. reported that in July 08 during summer vacation, while

Other Meds: Unknown

Lab Data: unknown. The following information was obtained through follow-up and/or provided by the government. 6/4/10 Neurology consultations received for dates of service 7/27/07 to 4/23/10. Labs and diagnostics: CBC, ALT, sodium-all normal. Bilir

History: PMH: epilepsy since age 10

Prex Illness: convulsion disorder

Prex Vax Illns:

Vaers Id: **389279-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	16-Nov-2009	18-Nov-2009	2	25-May-2010	26-May-2010	FR	WAES1005USA02336	26-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Generalised erythema, Hepatitis, Pyrexia

Symptom Text: Information has been received from Health Authority (ES-AGEMED-432366340) concerning a 10 year old female who on 16-NOV-2009 was vaccinated with a dose of GARDASIL (IM, batch # and site not reported) and a dose of PEDIATRIC TWINRIX (GSK, IM, batch # and site not reported). It was reported that on 18-NOV-2009 the patient started with pyrexia. On 19-NOV-2009 the patient presented a generalized erythema. On 20-NOV-2009 she had hepatitis. A blood test performed on 20-NOV-2009, total bilirubin 2.3; direct bilirubin 1.2. ALT: 719; GGT: 178; CRP: 17.7, the rest was normal. Sediment: urobili positive (+++). Abdominal sonogram performed on 03-DEC-2009 was normal. Blood test on 23-DEC-2009 was normal. Hepatitis serology was not performed. The patient recovered from hepatitis, generalized erythema and pyrexia on 23-DEC-2009. The case is closed. Case reported as serious by HA with other medically important condition as criteria. Other business partner numbers included E2010-03097.

Other Meds: Unknown

Lab Data: abdominal ultrasound, 03Dec09, normal; diagnostic laboratory test, 23Dec09, blood test was normal; serum C-reactive protein, 20Nov09, 17.7; serum alanine aminotransferase, 20Nov09, 719; serum direct bilirubin, 20Nov09, 1.2; serum gamma glut

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **389280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	M	14-May-2010	14-May-2010	0	25-May-2010	26-May-2010	NJ	WAES1005USA02669	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Hypersensitivity, Insomnia, Lip swelling, Swelling face

Symptom Text: Initial and follow-up information has been received from a physician and licensed practitioner nurse (office manager) concerning a 15 year old male patient with no pertinent medical history, concurrent conditions, or drug allergies who on 14-MAY-2010 was vaccinated with the first dose of GARDASIL (lot# 663559/1178Y). There were no concomitant vaccines or therapy. The physician stated that on 14-MAY-2010 the patient experienced facial swelling, similar to Stevens-Johnson syndromes but without the skin reaction, after his first vaccination with GARDASIL. The patient was seen in the Emergency Room where he received IV Benadryl and IV steroids and a MEDROL dose pack for home. The patient was not admitted to the hospital. The physician reported that the patient also had dizziness, headache and insomnia. The office manager reported that the patient had followed-up at the office on 19-MAY-2010. The patient still not totally recovered, but was doing better. The manager confirmed that the event was not Stevens-Johnson syndrome. The event was not considered disabling or life threatening by the office manager. The office was unsure if the next dose in the GARDASIL series would be given. "Facial swelling, dizziness, headache and insomnia" were considered to be other important medical events by the physician. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 5/26/10 MR received for dates 5/18/10 to 5/19/10 CC: f/u ER visit for reaction to vax. Pt has facial swelling. OV 5/19/10 f/u allergic reaction. CC: dizziness, HA, vertigo. Diag/Labs: abs neutrophils 12784(H), CRP 1.1(H). 6/3/10 Hospital record received for date 5/15/10 DX: allergic reaction. CC: lip swelling after vax this day. Assessment: swelling of lips only. IV treatment given pt stable at dc.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389284-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-May-2010	18-May-2010	0	25-May-2010	25-May-2010	NY		07-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0331Z	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Felt faint after HPV shot. Took 3 hrs to feel better. Slight dizziness 5/19/20.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389341-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-May-2010	25-May-2010	0	25-May-2010	26-May-2010	LA		04-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	06724	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ear discomfort, Headache, Visual impairment

Symptom Text: Patient was administered HPV. Approximately 5-7 mins, stated ears feel full, and seeing spots in front of me. B/P 118/79 70. Taken 15 mins later 126/54 P75 states H/A a 4(1-10 pain scale). Denies no other c/o's mom refused emergent care. MD was notified.

Other Meds: Birth control pills

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389342-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-May-2010	18-May-2010	0	25-May-2010	26-May-2010	CA		07-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3438AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1354Y	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3075AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope after 5-10 minutes after receiving the 3 shots.

Other Meds:

Lab Data: Patient was evaluate in ER sent home no w/u, reporter care

History:

Prex Illness: Cough, vomiting

Prex Vax Illns:

Vaers Id: **389343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	21-May-2010	Unknown		25-May-2010	26-May-2010	NM		04-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1377Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Pyrexia, Urticaria, Wheezing

Symptom Text: Wheezing, hives, slight fever, injection site redness, pain. Patient better without medical attention.

Other Meds: CELEXA; LEVOXYL; Doxycycline; MVI; Minocycline

Lab Data:

History: Asthma; Depression; Hypothyroidism

Prex Illness: None

Prex Vax Illns:

Vaers Id: **389349-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	26-Feb-2010	20-May-2010	83	26-May-2010	26-May-2010	FL		06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2928AA	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aggression, Dizziness, Grand mal convulsion, Headache, Loss of consciousness, Postictal state, Tongue biting, Tremor, Unresponsive to stimuli

Symptom Text: PATIENT SUFFERED A GRAND MAL SEIZURE AT SCHOOL. HIS SISTER ALSO RECEIVED THE VACCINE (VAERS ID 383436) AND HAD GRAND MAL SEIZURE ON 03/17/2010. SISTER'S SEIZURE WAS 85 DAYS AFTER HER FIRST SHOT, PATIENT'S WAS 83 DAYS AFTER HIS FIRST SHOT. The following information was obtained through follow-up and/or provided by the government. 06/09/10. Neurology consult for DOS 05/21/10. Pt was seen after experiencing 1 seizure episode. Seizure was preceded by possible auditory hallucinations, unresponsiveness, unconsciousness and shaking. Pt had HA, dizziness. Assessments: seizures. Pt scheduled for f/u appointment and MRI. 06/30/10. ER report for 05/20/10. Pt p/w seizure, lightheadedness, HA. DX: possible sz. Pt discharged with a f/u appointment with neurologist. On 06/02/10, Pt had another ER visit after having a second episode of tonic-clonic seizure. Pt was postictal and bit tongue. Impression: recurrent seizures with no recent finding or intracranial bleed or mass or metabolic reason. Pt experienced 2 other seizure episodes while in ER. Tx: Ativan, Kepra. Pt was also combative after the seizure. Pt stabilized. Pt discharged home and to follow up with a neurologist. 08/03/10. Radiology exam on 05/25/10. Pt underwent brain MRI after the new onset of seizures. Impression: very small subcentimenter focal area of high signal in R posterior parietal deep white matter with nonspecific focal area edema, demyelination, no mass. Radiologist considered this finding could be related to h/o new onset seizures, however it could also be incidental finding.

Other Meds:

Lab Data: EEG, CAT SCAN, BLOOD WORK-ALL NORMAL; STILL WAITING ON MRI RESULTS. The following information was obtained through follow-up and/or provided by the government. DX studies: EEG normal. MRI of brain abnormal.

History: NO The following information was obtained through follow-up and/or provided by the government. PMH: none. Allergies: Ibuprofen, Gardasil.

Prex Illness: NO

Prex Vax Illns: GRAND MAL~HPV (Gardasil)~2~15.08~Sibling

Vaers Id: **389351-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	23-Jul-2009	23-Jul-2009	0	26-May-2010	27-May-2010	FR	WAES0908USA01792	27-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Cervix oedema, Complication of pregnancy, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer for the GARDASIL vaccine pregnancy registry concerning a 26 year old female patient who was vaccinated with the third dose of GARDASIL (batch # not reported) via intramuscular route on 23-JUL-2009. The day following vaccination the patient found out that she was pregnant. Her latest menstrual period dated back to 18-JUN-2009. No reaction was reported. Follow up information has been received on 10-FEB-2010: The patient was contacted by phone and had informed that everything was ok, currently the pregnancy was on the 34 week without any clinical incidents. The delivery was scheduled for nineteenth or twentieth of March. Follow up information received from a consumer on 14-MAY-2010: The patient was contacted by phone with success. The patient gave birth to a male baby on 17-FEB-2010 (35th week). It was the first pregnancy of the patient. The physician decided to conduct a caesarean because the baby was too much fit in and the mother had developed a cervical oedema. The baby apgar 10/10, both the baby and the mother were well. No more information is expected. File is closed. The event was reported as other medically significant condition. Other business partner numbers include: E2009-07879. No further information is available.

Other Meds: unknown

Lab Data: Apgar score, 10/10

History:

Prex Illness: Pregnancy NOS (LMP = 18Jun09)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389445-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	16-Apr-2010	16-Apr-2010	0	26-May-2010	27-May-2010	CA		04-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Malaise

Symptom Text: 25 yo female received 3rd dose GARDASIL on 4/16/10. She calls in today c/o that she felt approximately 1 hr after getting the shot. (she was under observation here x 20-25 min). C/o sickness, chest pressure->Went to ER 2 days later->no specific treatment. Currently asymptomatic.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389450-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	18-May-2010	20-May-2010	2	27-May-2010	27-May-2010	GA		31-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy, Swelling

Symptom Text: Swelling to right deltoid. Lymphadenopathy to Rt. axilla and Rt. neck - cervical lymph node.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389491-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		27-May-2010	28-May-2010	FR	WAES1005USA02998	28-May-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diaphragmatic paralysis

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route, and lot# not reported). The physician reported that she administered three times GARDASIL to the patient and the patient had signs of diaphragm paralysis. The patient's outcome was unknown. No detailed information available at the moment. The reporter felt that diaphragm paralysis was related to therapy with GARDASIL. Diaphragm paralysis was determined to be an other important medical event by the reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389509-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-May-2010	26-May-2010	0	27-May-2010	27-May-2010	CA		06-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0216Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives on neck and face.

Other Meds: None

Lab Data: None

History: None

Prex Illness: Acne

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389511-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	11-May-2010	11-May-2010	0	27-May-2010	27-May-2010	LA		09-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB373AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1332Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Received GARDSASIL #1 on 5/11/10 in (R) deltoid. Pt returns today with complaints of (R) arm pain at injection site. No redness, swelling, heat or hardness noted.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **389519-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-May-2010	21-May-2010	1	27-May-2010	28-May-2010	NC		07-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Eczema, Eye swelling, Pruritus, Urticaria

Symptom Text: Received GARDASIL #2 on 5 20 2010. On 5/21/2010, developed hives, pruritis, periorbital swelling. Pre-existing condition of eczema exacerbation. As of 5/25/2010, no improvement of symptoms. Pt advised to call Dermatologist.

Other Meds:

Lab Data:

History: Eczema

Prex Illness: None

Prex Vax Illns:

Vaers Id: **389537-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-May-2010	26-May-2010	0	28-May-2010	28-May-2010	TX		07-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Computerised tomogram normal, Convulsion, Dizziness, Fall, Laboratory test normal, Muscle twitching

Symptom Text: Pt had a dizzy spell, fell down and about 20-30 sec later had a seizure involving all extremities and twitching of mouth and eyes lasted for approx 1-2-min. Pt was transferred to ER. CT scan / labs - normal. Discharged.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389576-1** **Related reports:** 389576-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Aug-2007	Unknown		28-May-2010	28-May-2010	IA		09-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0244U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Headaches after 1st GARDASIL shot.

Other Meds:

Lab Data: MRI

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389576-2** **Related reports:** 389576-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Aug-2007	Unknown		07-Jun-2010	07-Jun-2010	IA		07-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB179AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	02446	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Headaches started after 1st GARDASIL and Hep A shot.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389579-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-May-2010	17-May-2010	0	28-May-2010	28-May-2010	IN		06-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Pallor

Symptom Text: Mom called from the room for help. When we came in the pt had fallen from the bed to the floor. She was pale. We rolled her over and woke her back up. Lifted her feet and gave her cold water and a sucker. She layed on the floor for about 5-10 minutes. Dr. looked her over and said she looked fine.

Other Meds: ZYRTEC one dly; EPI-PIN prn

Lab Data:

History:

Prex Illness: Left side rib pain

Prex Vax Illns:

Vaers Id: **389648-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	03-Jan-2008	03-Jan-2008	0	29-May-2010	02-Jun-2010	MD		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0530U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Back pain, Condition aggravated, Depression, Dizziness, Dyspnoea, Educational problem, Hypersensitivity, Musculoskeletal stiffness, Nausea, Neck pain, Neurological symptom, Pallor, Weight increased

Symptom Text: Before I received the shot, I was a normal, healthy and very active teenager and an excellent student. After the shot, everything changed. My former gynecologist gave me the shot and when I came back 3 days later to tell her what had happened (I'll explain after this), she denied giving me the shot and basically said that there was nothing she could do to help me. I had a severe allergic reaction a few hours after the first shot. I had severe nausea, severe dizziness, and severe shortness of breath. I also was extremely pale and thought that and felt like I was going to pass out. I was taken to the emergency room by my mother and they determined that it was a severe allergic reaction to the shot and suggested to me not to get the second or third shot, which I never did. The following day, I woke up with severe pain and stiffness throughout my whole body, where it was most severe in my entire neck and my entire back. I had never ever had pain this severe in my life until the day after I got the shot and I believe that they are related. I have had the severe pain ever since. It has completely and negatively affected my entire life. I was no longer able to be active, I gained weight, and my grades dropped dramatically. It has also affected my depression at some points and makes it worse sometimes, when before the medication that I am on, worked all of the time, until I had this severe neck and back pain, which at times, has made my depression worse. I am still having a lot of trouble with all of this horrific pain. It has completely debilitated me and I am at a loss for what to do next, because I have tried almost everything in the book, minus surgery. The following information was obtained through follow-up and/or provided by the government. PCP medical records received 6/22/10. Service dates 1/3/2008 to 7/15/08. Assessment: Neurological symptoms. Patient had appointment for refills of oral contraceptive rx. She is having neurological symptoms since first gardasil vaccine on 1/3/08.

Other Meds: -Lexapro 20mg/day -Clonopin .5mg as needed for anxiety -Hydrocodone/APAP 10mg/325mg 1 every 8hours -Lyrica 200mg 3 times a day -Maxalt 10mg 1-2 as needed for migraines -Vyvanse 50mg 1/day for concentration

Lab Data:

History: same as listed above in the beginning of my statement. (Depression [before the shot], and allergies- hay fever in the spring [like grass/tree pollen, etc... and cats).

Prex Illness: I was diagnosed with clinical depression in December/January of 2002/2003. That is the only illness that I was diagnosed with, w

Prex Vax Illns: severe allergic reaction and severe neck/back pain the following day and still going on today(almost 3 years)~HPV (Gardasil)~1~19.17~Patient

Vaers Id: **389657-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-May-2010	29-May-2010	1	31-May-2010	01-Jun-2010	NJ		01-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	UNKNOWN MANUFACTURER	NULL	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Chills, Lethargy, Malaise, Nausea, Pain, Pyrexia

Symptom Text: Lethargy, nausea, general feeling of illness which progressed to severe body aches, chills, fever over 100, weakness.

Other Meds: None

Lab Data:

History: None

Prex Illness: Dizziness leading to having to lay down immediately for 10 minutes. Severe pain at shot site.

Prex Vax Illns: None~ ()~~0.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389735-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		01-Jun-2010	02-Jun-2010	FR	WAES1005USA04311	02-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia universalis, Tonsillitis

Symptom Text: Case received from a health care professional. This case was poorly documented. A gynecologist reported that an adolescent female patient of unspecified age was vaccinated with a dose of GARDASIL (lot # not reported) on an unspecified date. On an unspecified time post vaccination the patient developed a tonsillitis and subsequently generalized alopecia universalis. Further course, duration and outcome were not reported. Tonsillitis and generalized alopecia universalis was reported by gynecologist to be an other important medical event. Other business partner numbers included E2010-03248. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **389743-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-May-2009	20-Sep-2009	123	01-Jun-2010	01-Jun-2010	IA		08-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Alopecia, Arthralgia, Fatigue, Headache, Heart rate abnormal, Hypoaesthesia, Syncope

Symptom Text: 4 months after 3rd shot got 24 hour headaches. Other symptoms then started- fatigue, hair loss, numbness in hands and feet, joint pain, fainting, rapid heart rate, POTS, now at 9 months after shot started stomach issues. It hurts after eating anything.

Other Meds: SINGULAIR

Lab Data: Cat Scan; 2 MRI's; tilt table test; ultrasound on

History: allergic to BACTRIM and Amoxicillin

Prex Illness:

Prex Vax Illns:

Vaers Id: **389745-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-May-2010	25-May-2010	0	01-Jun-2010	01-Jun-2010	IN		08-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1099Y	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3081AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041BA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1328Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood blister, Contusion, Eyelid oedema, Fall, Head injury

Symptom Text: Vaccinations administered at approximately 2:20 pm. Pt. was instructed to remain seated. I was speaking to pt.'s mother for approximately 10 min. when episode occurred. Pt. did not state feeling ill or faint. Suddenly, she rolled forward out of chair onto floor. Head struck floor (slightly puffy over L eyes et slight bruise L cheek) 1-2mm blood blister on R index finger after fall.

Other Meds:

Lab Data:

History: (Petit Mal Seizures to age 2 yrs and stopped); Neomycin ear drops

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389756-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-May-2010	19-May-2010	0	01-Jun-2010	01-Jun-2010	GA		01-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
HEPA	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
VARCEL	UNKNOWN MANUFACTURER	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Immediate post-injection reaction, Loss of consciousness, Unresponsive to stimuli

Symptom Text: Patient collapsed immediately following the Gardasil shot. She fell to her right side. Her mouth dropped open and her eyes were open. She was nonresponsive. She came to after a minute or two and said everything went black - sort of like she fainted but her eyes were not closed.

Other Meds: I could not find Gardasil listed but she had the first dose on 8/5/2008 and the second dose on 10/13/2008.

Lab Data: The doctor ordered an EKG which found her heart rate to be normal.

History: no

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389757-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jun-2010	01-Jun-2010	0	01-Jun-2010	01-Jun-2010	OK		01-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1178Y	1	Right arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B053BB	0	Right arm	Unknown	
VARCEL	MERCK & CO. INC.	1593Y	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Rec'd telephone call fpm patient mother about 1/2 hour after they left. Mother staes patient has whelps on her body and her tongue. Advise mother if she had Benadryl to give now and take her to the E.R.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389774-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	26-May-2010	27-May-2010	1	01-Jun-2010	01-Jun-2010	AR		05-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y		Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061CA		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3088AA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling, Oedema peripheral, Tenderness

Symptom Text: Swelling and tender to touch in left arm and some swelling in periorbital.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389801-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	24-May-2010	24-May-2010	0	02-Jun-2010	02-Jun-2010	MO	MO201012	03-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus

Symptom Text: Patient received HPV around 4:40 pm 5/24/10. States she developed itching interior aspect of both thighs around 9:00 p.m. on 5/24 with raised reddened areas on interior thighs, posterior aspect right axilla and small area right forearm; larger area left forearm. Used Benadryl itch cream. Still demonstrating symptoms around 3:30 on 5/25 when came to health department.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 389803-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Sep-2009	08-Sep-2009	0	02-Jun-2010	03-Jun-2010	HI	WAES0912USA01212	04-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y		Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Decreased appetite, Dizziness, Duodenal ulcer, Dyspepsia, Headache, Inflammation, Myalgia, Nausea, Pain

Symptom Text: Information has been received from a physician concerning a female who developed "duodenal ulcer" after receiving GARDASIL (lot # not available). The patient had spoken to physician. At the time of the report, the patient's status was unknown. Follow up information received from a physician concerning a 14 year old female with urinary tract infection. Exercise-induced asthma and no known drug allergies, who on 08-SEP-2009 was vaccinated with a dose of GARDASIL (lot # 662404/0312Y, IM) in the left arm at 2:15 p.m. Concomitant therapy included BACTRIM started on 08-SEP-2009 after GARDASIL vaccine was given for urinary tract infection. On 08-SEP-2009 the patient experienced nausea, myalgia, headache, dizziness lasting 6-8 weeks (especially the nausea), the patient was treated with zofran, ranitiding without relief. The patient was seen by gastroenterologist and had EGD done on 15-OCT-2009 which showed duodenal ulcer. Currently she continued to have nausea, headache despite being on NEXIUM. It was reported on 28-SEP-2009 from a medical record that she was in her normal state of health until three and a half weeks ago. Within hours of receiving GARDASIL, the patient began to have abdominal pain, nausea, dizziness, headaches, and body aches. The problems with abdominal pain and nausea had been constant for the past three and a half weeks. The patient stated that the nausea was constant, but she had had no vomiting. Her appetite had also been significantly less, she denies vertigo. The patient stated that her abdominal pain was worse after eating. She tried ZANTAC, which did not help with her pain or nausea. ZANTAC made her more dizzy. The patient also had persisting intermittent headaches and dizziness. Her body aches had resolved. The patient reported that her stools were soft and daily. She denied any history of constipation. Current medications included ALBUTEROL as needed. The patient would undergo a colon clean-out, start daily stool softener therapy, bowel retraining, and increased dietary fiber. For her colon cl

Other Meds: BACTRIM

Lab Data: esophagogastroduodenosc, 10/15/09, showed duodenal ulcer; esophagogastroduodenosc, 03/31/10, showed a normal esophagus, stomach, and 2nd portion duodenum; duodenal biopsy, 03/31/10, showed some inflammation still in area where previous eros

History:

Prex Illness: Urinary tract infection; Asthma exercise induced

Prex Vax Illns:

Vaers Id: **389804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-May-2010	20-May-2010	0	02-Jun-2010	03-Jun-2010	TX	WAES1005USA03033	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF486AA		Left arm	Intramuscular	HPV4
	HPV4	MERCK & CO. INC.	0216Y	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Crying, Cyanosis, Loss of consciousness, Malaise, Muscle tightness, Musculoskeletal stiffness, Presyncope, Surgery, Syncope, Unresponsive to stimuli, Urinary incontinence

Symptom Text: Information has been received from a physician and a registered nurse concerning an eighteen year old female patient who on 12-MAY-2010, 18-JUL-2008 and 20-MAY-2010 was vaccinated with the first, second and third doses of GARDASIL (Lot # 659962/1740U, Lot # 659182/1757U and Lot # 663451/0216Y 0.5 ML, respectively) into the right arm. On 20-MAY-2010, the patient also received a dose of ADACEL (Lot # UF486DA) into the left arm. About 5 minutes after the third dose of GARDASIL had been administered, the patient sat down in the waiting room. The patient developed a "little" seizure. The nurse reported that the patient lost consciousness, became stiff in the legs and had clinched hands. The patient had cyanosis and was incontinent of urine. The registered nurse was not sure how long the seizure had lasted. The patient regained consciousness and recovered. The patient's mother stated that on the evening of 20-MAY-2010 the patient had seemed a little "off" (not specified). The patient was referred to two different Neurologist physicians but the patient's mother had stated that the patient had not made an appointment with either Neurologist at that time. The patient was also advised to contact the Pediatric Cardiologist office to schedule an electrocardiogram ECG. On 24-MAY-2010, the registered nurse stated that the patient's mother was contacted via a telephone call. The patient's mother stated that the patient was "doing fine". On 25-MAY-2010, the nurse stated that the patient's father had told the physician that the patient had surgery in 2009. The patient received IV therapy and passed out. The patient's father thought that at that time the patient had a seizure. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 06/03/10. PCP visit on 05/20/10. Pt had syncopal episode after immunization, arching, urinary incontinence, unresponsive, crying, seizure,

Other Meds: Unknown

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: ECG on 05/27/10: normal. MRI and EEG negative for seizures or any abnormality.

History: The following information was obtained through follow-up and/or provided by the government. PMH: syncope, muscle jerks.

Prex Illness:

Prex Vax Illns:

Vaers Id: **389805-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	22-Apr-2010	01-May-2010	9	02-Jun-2010	03-Jun-2010	FR	WAES1005USA04308	03-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1400U	0	Left arm	Intramuscular	
	TBE	UNKNOWN MANUFACTURER	106021A	2	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dysaesthesia, Headache, Nausea, Vision blurred

Symptom Text: Case received from health care professional. A pediatrician reported that a 20-year-old female patient was vaccinated with a first dose of GARDASIL (lot # 1400U, batch # NH38510) IM into the left upper arm and concomitantly with a third dose of ENCEPUR (lot # 106021A) IM into the right upper arm on 22-APR-2010. On 01-MAY-2010 the patient developed headache and dysaesthesia in the hairy area of the head. On 04-MAY-2010 she additionally experienced nausea and on 07-MAY-2010 she had blurred vision. For further investigations the patient was admitted to hospital for an unspecified time. The patient recovered from blurred vision after one day and from the other symptoms on 11-MAY-2010. Previous vaccinations with ENCEPUR on 08-MAY-2009 first dose and on 18-JUN-2009 second dose were well tolerated. Other business partner numbers included E2010-03226. No further information is available. Case closed.

Other Meds: unknown

Lab Data: unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389806-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Jun-2010	03-Jun-2010	FR	WAES1005USA04360	03-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Completed suicide, Death

Symptom Text: Information has been received from a health professional, via the Program for Appropriate Technology (PATH), concerning a female patient who on an unspecified date, was vaccinated with the third dose of GARDASIL. Subsequently, on an unspecified date, the patient committed suicide. The cause of death was suicide. At this time, relationship of suicide death to GARDASIL is unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **389807-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	29-Apr-2010	01-May-2010	2	02-Jun-2010	03-Jun-2010	FR	WAES1005USA04579	03-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Demyelination, Grip strength decreased, Injection site pain, Monoparesis, Multiple sclerosis, Spinal cord disorder

Symptom Text: Information has been received from a Neurologist (reference number TMI-2010-200) and a pharmacist concerning an 18 year old female patient who 3 weeks before 20-MAY-2010, was vaccinated with the first dose of GARDASIL (intramuscular in left deltoid). Three weeks before vaccination, in April 2010, the patient had experienced Paraesthesia in the right thigh which lasted for about 15 days. The patient consulted a general practitioner which was not worried about it. The patient was asymptomatic for about ten days before vaccination. After the administration of the vaccine, the patient experienced pain at the injection site and 2 days later a very slight paresis of the upper left limb appeared: the patient now needed 2 hands to press a shampoo bottle. The general practitioner was consulted and again he was not worried. Her mother, a neurology nurse, was worried and consulted a neurologist who diagnosed a demyelination disease: -acute disseminated encephalomyelitis (but 2 episodes) or -multiple sclerosis (lesion at corpus callosum specific to multiple sclerosis + cervical spinal lesion). The neurologist stated that, in her opinion the disease had started before the administration of the first dose of GARDASIL. The patient has a twin sister. The sister received the first dose of GARDASIL 14 days later than the patient and did not present any symptoms. No other relevant personal or family history. The case was upgraded to serious as it concerns a medically important condition. Other business partner numbers include E2010-03270. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Paraesthesia lower limb

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Jun-2010	02-Jun-2010	0	02-Jun-2010	02-Jun-2010	TX		04-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Teen fainted, recovered, then fainted again in office after receiving her 3rd GARDASIL (HPV). Teen ate breakfast before office visit.

Other Meds: Benzacline

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 389885-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	18-May-2009	21-May-2009	3	02-Jun-2010	03-Jun-2010	NY		03-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Burning sensation, Depression, Fatigue, Hypoaesthesia, Irritability, Multiple allergies, Pain in extremity, Paraesthesia

Symptom Text: Severe pain extremeties- numbness tingling, burning fatigue, developed allergies gluten, sugar, casein, fatigue, irritability, depression, abdominal pain.

Other Meds: Allese birth control

Lab Data: brain spine MRI EMG complete blood panels including SLE, ANA lyme disease

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **389903-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-May-2010	20-May-2010	1	03-Jun-2010	04-Jun-2010	GA	WAES1005USA04402	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0313Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint swelling, Lip swelling, Oedema peripheral, Reaction to previous exposure to any vaccine

Symptom Text: Information has been received from a licensed practical nurse concerning an 18 year old female patient with red dye and penicillin allergy who on 17-MAR-2010 and 19-MAY-2010 was vaccinated with a first and second dose of GARDASIL (Lot # 662724/0313Y for both doses), 0.5 mL, IM. Concomitant therapy included LOESTRIN 24 FE. The nurse reported that on 20-MAY-2010 the patient had experienced swollen bottom lip, heel, hip, and wrist after receiving the second dose of GARDASIL. She had been taking BENADRYL. The patient called the office. At the time of this report, the patient was recovering. The licensed practical nurse considered "swollen bottom lip, heel, hip, and wrist" to be other important medical events. It was also stated that the patient had similar reaction when she was little with an unknown medication. Additional information has been requested.

Other Meds: LOESTRIN 24 FE

Lab Data: None

History:

Prex Illness: Iodine allergy; Penicillin allergy

Prex Vax Illns:

Vaers Id: **389904-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jul-2009	01-Jul-2009	0	03-Jun-2010	04-Jun-2010	TX	WAES1005USA04198	04-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Bronchospasm, Cognitive disorder, Fatigue, Hypersensitivity, Infection susceptibility increased

Symptom Text: Information has been received from a physician concerning a 19 year old female who in July 2009 and December 2009, was vaccinated with the first and second doses of GARDASIL, respectively. The patient experienced one week of feeling exhausted and brain fog after receiving her first dose of vaccine. She experienced severe brain fog and profound fatigue after the second dose. She was not able to attend spring semester of college as a result. Prior to receiving GARDASIL she was an athlete who excelled at track and excelled as a student and did not have an allergy to citrates prior to receiving GARDASIL. The patient was also experiencing a severe hypersensitivity to citrates and seemed to be more prone to Streptococcus infections. The physician also reported the patient just recently experienced intense bronchospasm for 1 hour after taking a lactobacillus mixture. It was discovered after the patient's reaction that the mixture contained an extremely small amount of citrate. At the time of report the patient had not recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **389905-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		03-Jun-2010	04-Jun-2010	--	WAES1005USA04197	04-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from an office manager concerning her niece (a female autistic patient) who on unspecified date was vaccinated with the first and second dose of GARDASIL. It was reported that "after receiving the first and second dose of vaccine the patient experienced four to five seizures. The office manager stated that the patient had recovered. The office manager also stated that the patient went to a completely different office (medical practice) and they did not treat her at their office". At the time of report the patient had recovered. Upon internal review, seizure was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Autism

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389906-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	28-May-2010	28-May-2010	0	03-Jun-2010	04-Jun-2010	FR	WAES1005TWN00062	04-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy, Loss of consciousness, Tonic convulsion

Symptom Text: Information has been received from a physician concerning a 27 year old female who on 28-MAY-2010 was vaccinated with the third dose of GARDASIL at her left upper arm in the clinic. One minute after vaccination, the patient experienced seizure attack lasting 2-3 minutes. Loss of conscious, and tonic convulsion with upgaze was observed. Subsequently, the patient recovered from seizure attack. Afterward the patient was sent to emergent room for further care. The reporter felt that seizure attack was related to therapy with GARDASIL. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389932-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-May-2010	26-May-2010	0	03-Jun-2010	03-Jun-2010	CA		03-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3020AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1659Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF544AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: GENERALIZED RASH, RESOLVED WITH DIPHENHYDRAMINE 25MG PO X1

Other Meds:

Lab Data:

History: NOONAN SYNDROME, MR, SEIZURE DISORDER

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389933-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	25-May-2010	25-May-2010	0	03-Jun-2010	03-Jun-2010	CA		03-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y		Left leg	Intramuscular	
	MNQ	SANOFI PASTEUR	U320AA		Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF544AA		Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1659Y		Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: AFTER ADMINISTERING VACCINES TO THE PATIENT, THE PATIENT STOOD UP AND FELT LIGHT HEADED. I ASKED IF SHE WAS OK, SHE SAID NO AND SAT BACK DOWN. SHE WAS DIZZY AND FELT AS THOUGH SHE WAS GOING TO FAINT, BUT NEVER DID. AFTER 15 MINUTES AND SOME PO FLUIDS, SHE WAS WELL.

Other Meds:

Lab Data:

History:

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389946-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Jun-2010	02-Jun-2010	0	03-Jun-2010	04-Jun-2010	MA		08-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1498Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort, Muscle spasms, Musculoskeletal stiffness

Symptom Text: Within one hour of receiving HPV vaccine pt developed (L) hip cramping & stiffness that have continued since, thus far <24 hours. No injury, no new activity or exercise. Pt states discomfort due to vaccine.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **389956-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	01-Jun-2010	02-Jun-2010	1	03-Jun-2010	04-Jun-2010	GA		09-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1159Y	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	1332Y	0	Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB359AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling, Injection site warmth, Rash macular

Symptom Text: On 6/2/10 around 4PM, client noticed redness "blotchy" on (L) arm where received TDAP & VZV vaccines. On 6/3/10 upon wakening at 9AM, client noticed hardness and swollen (L) deltoid area, continued redness, warm to touch. Back of upper (L) arm (where VZV given) is redness and small knot under the skin. Client placed cold rag on areas for 5 minutes 6/3/10 around 11AM.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **389986-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Mar-2010	05-May-2010	51	04-Jun-2010	07-Jun-2010	FR	WAES1005USA04580	07-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ28290	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Lymphadenopathy, Splenomegaly

Symptom Text: Information has been received from a gynaecologist concerning a 14-year-old female patient was vaccinated with a first dose of GARDASIL (Batch number NK31480, lot # NJ28290) IM into the upper arm on 15-MAR-2010. This batch was not released by HA. On 05-MAY-2010 the patient developed swelling for her neck lymph nodes and of spleen. The patient was admitted to hospital for further diagnostics. Laboratory values showed increased transaminases. Suspicion of mononucleosis was established, but not serologically confirmed. At the time of the reporting the patient was still hospitalized and had not recovered. Other business partner numbers include E2010-03325. No further information is available.

Other Meds: Unknown

Lab Data: laboratory test, ??May10, increased transaminases

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **389987-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-May-2010	18-May-2010	0	04-Jun-2010	07-Jun-2010	FR	WAES1005USA04581	07-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353X	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, Urticaria

Symptom Text: Case reported by health Authority (case no. 117380) (Local case n. IT243/10). Initial report received on 25-MAY-2010. An 11 year old female with no previous medical history reported was vaccinated on 18-MAY-2010 with the second dose of GARDASIL (lot number 1353X; batch number NL44120). On the same day, 1 hour post-vaccination, she presented with an urticarial reaction and respiratory difficulty. She was hospitalized and treated with BENTELAN 1 mg compress. The outcome was recovered on 18-MAY-2010. Other business partner numbers include E2010-03321. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390005-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-May-2010	25-May-2010	0	04-Jun-2010	04-Jun-2010	TX		04-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1377Y	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral, Pain in extremity

Symptom Text: Pt received the "GARDASIL" injection on 5/25/10 - her arm was swollen and painful. The swelling did go done but on 6/1/10 swelling and pain came back.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390018-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	27-May-2010	27-May-2010	0	04-Jun-2010	04-Jun-2010	PA		04-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt had syncope event shortly after receiving Gardasil vaccine in waiting area while leaving. No loss of bowel/bladder, no shaking or biting of tongue. LOC = approx. 10 sec. Paitient examined by physician. Pt counseled on symptoms of head trauma, to go to ED if any problems and not to sleep x4 hrs.

Other Meds:

Lab Data: Provider examination

History: NKDA or pre-existing conditions.

Prex Illness: No current illness

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390052-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	24-May-2010	Unknown		06-Jun-2010	07-Jun-2010	CA		07-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Delayed period.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: Delayed Menstrual Cycle~HPV (Gardasil)~1~0.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390079-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	30-Mar-2010	30-Mar-2010	0	07-Jun-2010	07-Jun-2010	MA		09-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Myalgia, Swelling face

Symptom Text: Pts entire body started to ache. Facial swelling and hard time breathing went to ED-given 2 doses of epinephrine.

Other Meds: Celexa; Ativan; Pentasa

Lab Data:

History: Crohns

Prex Illness: None

Prex Vax Illns:

Vaers Id: **390089-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Mar-2010	23-Mar-2010	1	07-Jun-2010	08-Jun-2010	FR	WAES1006USA00036	08-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEP	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Areflexia, Arthritis reactive

Symptom Text: Information was obtained on a request by the Company from the agency via a public case details form concerning an 11 year old female who on 22-MAR-2010 was vaccinated with a dose of GARDASIL. Secondary suspect therapy on 22-MAR-2010 included RECOMBIVAX HB (manufacturer unknown) by intramuscular route. On 23-MAR-2010 the patient experienced severe progressive reactive arthritis with loss of ability to walk and loss of ankle reflexes. The patient was admitted to hospital on 29-MAR-2010. The hands, elbows/knees and ankles were affected. The patient was treated with antiinflammatories. At the time of the report, the patient had not yet recovered. The agency considered that the events were possibly related to therapy with GARDASIL and RECOMBIVAX HB. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390092-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	04-Jun-2009	30-Jan-2010	240	07-Jun-2010	08-Jun-2010	FR	WAES1006USA00119	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1202U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Laboratory test, No reaction on previous exposure to drug, Urticaria

Symptom Text: Case received via a sales representative from a health care professional (GP) : A female had received the second or third dose of GARDASIL and experienced several flares of urticaria. Follow up information received from the same GP: Case upgraded to serious (other important event: use of intramuscular corticosteroids). A 29 year old female patient had received the third dose of GARDASIL (batch# NJ31210, lot# 1202U) in the left deltoid via intramuscular route on 12-JAN-2010. Starting 18 days after the vaccination and for a period of 2 months (i.e. from 30-JAN-2010 till 30-MAR-2010), the patient experienced several flares of urticaria. The patient had received a first dose of GARDASIL (batch# NJ31210, lot# 1202U) on 04-JUN-2009 and a second dose of GARDASIL (batch# NJ31210, lot# 1202U) on 19-AUG-2009. All doses were administered in the left deltoid via intramuscular route. The patient had no allergy, no medical history or risk factor, had not used medication in the month preceding the vaccination and had no adverse effect with previous vaccinations. The father had eczema. Vaccines had not been mixed with others in one syringe. A lab test was done but no result provided. The event was treated with antihistaminics and oral and intramuscular corticosteroids. The reporter did not tick any seriousness criteria but added a question mark under the word "serious" and added the comment" important urticaria"-work incapacity. The patient recovered. Other business partner numbers included: E2010-02605. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 390095-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Jun-2009	01-Apr-2010	296	07-Jun-2010	08-Jun-2010	FR	WAES1006USA00160	08-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1115U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Blood test normal, Conduction disorder, Demyelination, Feeling abnormal, Iron deficiency, Myelitis, Neuropathy peripheral, Paraesthesia, Rheumatoid factor negative, Sensory disturbance, Skin warm, Spinal cord injury thoracic, Tenderness

Symptom Text: Information has been received from a health authority (HA referenced number PEI2010014461) concerning a 16 year old female who on 15-MAR-2010 was vaccinated intramuscularly (site not reported) with third dose of GARDASIL (lot number 1316U, batch number NH3490). In the beginning of April 2010 (about two weeks before hospitalization), the patient developed tingling of her right toes spreading "stocking live" up to the right hip. On 25-APR-2010, the patient additionally developed "sensory disturbances" of the left toes and was admitted to the hospital. She reported that she had been more asthenic and less resilient recently. During clinical examination, she was tender to touch (in the area of tingling). Several investigations including electroencephalogram, MRI (cranial, cervical spine), visual evoked potential (VEP), ophthalmological examination and sonography of kidney and urinary tract showed normal results. The MRI of thoracic and lumbar spine showed an increased signal/lesion at the level of Th10. A focal myelitic event was suspected. The somatosensory evoked response (SEP) revealed a peripheral conduction disturbance in the right tibialis nerve. Blood count showed signs of iron deficiency and for the rest, normal values. Other laboratory tests revealed a decreased in ferritin (2ng/mL). CSF, proteins in serum and CSD were within normal limits. Oligoclonal bands in CSF were negative. Rheumatism serology revealed: anti-streptolysin of 406 U/mL. All other values were negative or normal. Neurotropic pathogens were negative in serum and CSF, except for cytomegalovirus antibodies IGg in serum 1:16T, CMV antibodies IgM in serum were borderline, rubella IgG in serum of 93, rubella antibodies (HHT) new 1:128. After a cortisone massive-dose therapy for five days, the symptoms improved and the physicians did not expect a CMV infection of rheumatic disease. Final diagnosis of acute thoracic demyelinating myelitis was established (onset was reported on the reporting form to be 12-APR-2010). On 03-MAY-2010, the patient was d

Other Meds: unknown

Lab Data: electroencephalography, ??Apr10, Normal; Magnetic resonance imaging, ??Apr10, Cranial and Cervical spine: Normal; visual evoked potential, ??Apr10, Normal; diagnostic laboratory test, ??Apr10, ophthalmological examination: Normal; ultrasoun

History: unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390111-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	12-May-2010	12-May-2010	0	07-Jun-2010	07-Jun-2010	OK		09-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C3352AA	0	Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	1436Y	1	Unknown	Unknown	
MNQ	SANOFI PASTEUR	U3077AA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	1099Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Infection, Injection site erythema, Injection site mass, Injection site swelling, Injection site warmth, Scratch

Symptom Text: Pt had a red swollen bump around injection site (R) SQ. Warm to touch. Pt came to office 5-25-10 still having problem. Dr. states pt had allergic reaction then scratched it causing an infection.

Other Meds:

Lab Data:

History: PCN; ADHD; BiPolar

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390120-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	23-Oct-2009	Unknown		07-Jun-2010	07-Jun-2010	CA		14-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0996Y	1	Unknown	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3047AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0249Y	0	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	U2937BA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pertussis

Symptom Text: Got pertussis 6/1/10.

Other Meds: None

Lab Data: Pertussis PCR

History: AR, healthy

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390151-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Jun-2010	05-Jun-2010	2	07-Jun-2010	08-Jun-2010	MA		10-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1336Y	2	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1178Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Local reaction

Symptom Text: 7 x 4.5 cm local reaction.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390180-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	01-Jun-2010	01-Jun-2010	0	08-Jun-2010	08-Jun-2010	WI		10-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB375AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1099Y	0	Left arm	Intramuscular	
MEN	SANOFI PASTEUR	U3097AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Walking out of exam room with mother and passed out in hallway.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390181-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	M	28-May-2010	29-May-2010	1	08-Jun-2010	08-Jun-2010	OK		10-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049BA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3075AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema multiforme, Rash morbilliform

Symptom Text: Pt developed morbilliform rash on face -> trunk -> extremities, onset about 12 hour after vaccines. Evolved to erythema multiforme rash without mucosal involvement. 2 ER visits (5/29 & 5/30), Rx with Diphenhydramine & Ranitidine.

Other Meds: Oral CLINDAMYCIN previous 5-6 days.

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 390185-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	26-May-2010	27-May-2010	1	08-Jun-2010	08-Jun-2010	MI		10-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Diarrhoea, Dizziness, Dyspepsia, Flatulence, Nausea

Symptom Text: C/O stomach pain, dizziness, diarrhea since receiving #1 dose of HPV vaccine on 5-26-10. Had OV 6-3-10 c/o the above symptoms along with excessive flatulence, heartburn and nausea. No vomiting.

Other Meds:

Lab Data: None

History: Allergy: PCN

Prex Illness: Hip pain; Is dieting and if goes without eating c/o dizziness and "sick" feeling

Prex Vax Illns:

Vaers Id: **390200-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		08-Jun-2010	09-Jun-2010	FR	WAES1005USA04506	09-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Injury, Syncope, Thoracic vertebral fracture, Urinary incontinence

Symptom Text: Background: A foreign HPV vaccination program commenced in May 2007 for females aged 12-26 years. Syncope and syncopal seizures can occur with any painful stimulus. High rates of both have been documented post GARDASIL vaccination. Aim: To describe cases of 'syncope' and 'seizures' post GARDASIL vaccination notified to SAEFVIC. Methods: All reports of adverse events following immunization (AEFI) received by SAEFVIC between May 2007 - April 2009 were selected for analysis. AEFI following GARDASIL vaccine coded as seizure or syncope were reviewed. Results: During the study period, 6% (9711653) of all SAEFVIC reports met the criteria: afebrile seizures (3), syncopal seizures (31) and syncope alone (63). Median age at vaccination was 15 yrs (range 8-30 years). 23% (7131) of syncopal seizures had associated urinary incontinence. An injury was sustained in seven cases, including one vertebral (T5TT6) fracture. After clinical review, further GARDASIL vaccine doses were given under supervision whilst lying down for 20 minutes to 21 women with no recurrences. The rate of syncopal seizures was 2.6 per 100,000 doses of GARDASIL vaccine distributed. Conclusion: A high rate of syncope and syncopal seizures was seen post GARDASIL vaccination in one location. Clinical follow-up allows for clarification of the diagnosis, a physical examination and investigations as appropriate. Effective strategies to minimize the risk of recurrent syncope post vaccination include lying down before and 20 minute post vaccination. Upon internal review T5/T6 vertebral fracture was considered to be an other important medical event. Attempts are being made to identify the additional patients in this abstract. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **390201-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.7	M	21-Oct-2008	21-Oct-2008	0	08-Jun-2010	09-Jun-2010	--	WAES0811USA00264B1	11-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Death, Drug exposure during pregnancy, Sudden infant death syndrome

Symptom Text: Information has been received from a nurse concerning an 8 month old male baby. The baby's 23 year old mother was vaccinated intramuscularly in the left deltoid with one 0.5 ml dose of GARDASIL (Lot #660618/0572X) on 21-OCT-2008. The mother's LMP was 22-SEP-2008. Estimated date of delivery was 29-JUN-2009. On 16-JUN-2009 the mother had a repeat scheduled Cesarean section, and delivered the male baby, weighing 7 pounds, 6 ounces. There was "no indication of any problems with the baby." The mother had no significant medical history, prenatal complications, and was not taking any concurrent medication according to the nurse. However, in February 2010, at about 8 months of age, the baby died of sudden infant death syndrome (SIDS). The nurse had no further information on this. A lot check was initialized. The mother's experience was captured in WAES #0811USA00264. Additional information is not expected.

Other Meds: iron (unspecified); vitamins (unspecified)

Lab Data: Unknown

History: Caesarean section

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390202-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	11-Aug-2009	Unknown		08-Jun-2010	09-Jun-2010	--	WAES0908USA03205B1	09-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ankyloglossia congenital, Drug exposure during pregnancy

Symptom Text: Information has been received concerning a baby whose mother was vaccinated on 11-AUG-2009 with a dose of GARDASIL during pregnancy. The mother's concomitant therapy included VAXA MIGRIN. It was reported that the baby was tongue tied but it was significant. It was unknown if the patient sought medical attention. At the time of the reporting, the patient's status was unknown. The mother's experience has been captured in WAES# 0908USA03205. Additional information has been requested.

Other Meds: VAXA MIGRIN

Lab Data: Unknown

History:

Prex Illness: Migraine

Prex Vax Illns:

Vaers Id: **390203-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	22-May-2010	22-May-2010	0	08-Jun-2010	09-Jun-2010	NY	WAES1006USA00383	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1778Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Hypersensitivity, Loss of consciousness, Pruritus, Swelling, Swelling face, Syncope, Urticaria, Vaginal haemorrhage

Symptom Text: Information has been received from a physician concerning a 25 year old female who on 22-MAY-2010, Saturday, was vaccinated with GARDASIL from a different Physician. On 27-MAY-2010, Thursday, the patient presented with hives on her body and some swelling (onset date also reported as 22-MAY-2010). The patient saw her original physician and was prescribed ZYDOL. Later that evening the patient fainted and went to the emergency room. While at the emergency room the patient was given prednisone and BENADRYL. Later that evening the patient had severe swelling among the face and she was admitted to the emergency room again and was hospitalized. On Sunday, 30-MAY-2010, the patient saw the reporter with severe pain in her abdomen and vaginal bleeding. At the time of the reporting, the patient's status was unknown. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 6/15, 6/16, and 6/22/10 ED and OPV records received for dates of service 5/22/10 to 5/30/10. Dx: Allergic Rxn. Presented to ED with c/o rash to face, arms and chest. Pain scale 2/10. Treated with IV Solumedrol and Benadryl. Discharged home in improved condition. Pt. presented to PCP with c/o allergic rxn. Hives all over body. Taking Xyzal. Red raised wheals getting bigger. Very itchy. When pt. got up at night whole body was swollen, pt, felt lightheaded and fell to the floor with loss of consciousness-fainted. Mother called ambulance and pt. taken to ED. Treated and released. Pt. returned to ED once more for facial swelling. To see allergist.

Other Meds: Unknown

Lab Data: Unknown. The following information was obtained through follow-up and/or provided by the government. 6/15, 6/16, and 6/22/10 ED and OPV records received for dates of service 5/22/10 to 5/30/10. Labs and diagnostics: Hgb 11.7 (L), RBC 3.7 (L

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390204-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Jun-2010	09-Jun-2010	--	WAES1006USA00607	09-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot# not reported) while she did not know that she was pregnant. The patient had a miscarriage. Unspecified medical attention was sought. At the time of this report, the patient's outcome was not reported. Miscarriage was considered to be an important medical event by the reporter. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **390229-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-May-2010	28-May-2010	0	08-Jun-2010	08-Jun-2010	TN		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF484CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	
	MEN	SANOFI PASTEUR	U3010AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Chest pain, Dizziness, Feeling hot, Headache, Hypoaesthesia, Immunisation reaction, Paraesthesia, Reflux oesophagitis

Symptom Text: Patient began complaining of (R) foot and leg numbness around 6 PM the day the vaccine was given. Patient developed headache and sensation of heat on back of head around the same time 2 days later, the patient complained of numbness in (R) hand that spread to (L) hand. The next day, the heat on her head and a feeling of lightheadedness prompted an ER visit. The following day, she returned to ER due to no improvement. The following information was obtained through follow-up and/or provided by the government. 6/9, 6/11 & 6/16/10 ED and OPV records received for dates of service 5/28/10 to 6/2/10. Dx: Disturbance of skin sensation, Headache. R arm numbness, R leg numbness. Medication Reaction. Immunzation Reaction. Presented to ED on 5/31/10 with c/o R arm and R leg numbness for a duration of 2 days, moderate in intensity which started with her menstral cycle. On 6/1/10 presented to ED with RUE warming, burning sensation and HA. On 6/2/10 presented to ED with c/o numbness to R arm and leg, radiating to L arm and leg occuring episodically also with hot sensation to the back of head. Also c/o feeling chest pain 2 hours after vaccination. Seen on 6/2/10 by PCP, with same c/o in addition to increased reflux.

Other Meds: Ranitidine 150 mg PO BID; Ibuprofen 800 mg PO QIP PRN

Lab Data: Per patient, an EKG, CT scan and blood work was done in the ER. The following information was obtained through follow-up and/or provided by the government. 6/9, 6/11 & 6/16/10 ED and OPV records received for dates of service 5/28/10 to 6/2/

History: None. The following information was obtained through follow-up and/or provided by the government. 6/9, 6/11 & 6/16/10 ED and OPV records received for dates of service 5/28/10 to 6/2/10. PMH: GERD

Prex Illness: Reflux and constipation

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390243-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	07-Jun-2010	08-Jun-2010	1	08-Jun-2010	09-Jun-2010	IN		09-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Hyperhidrosis, Nausea, Oedema peripheral

Symptom Text: Swelling of both hands, nausea, sweating, headache.

Other Meds: Gardasil

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: 390296-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	31-Mar-2010	24-May-2010	54	09-Jun-2010	10-Jun-2010	KY	WAES1006USA00385	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1377Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypothyroidism, Multiple sclerosis

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female with congenital adrenal hyperplasia- late onset 17 years no treatment or follow up since diagnosis, and penicillin allergy, who on 31-MAR-2010 was vaccinated with a first dose of GARDASIL (IM, lot # 665768/1377Y). Concomitant therapy included methotrexate and hormonal contraceptives (unspecified). No other vaccines were administered. On 04-MAR-2010, magnetic resonance imaging (MRI) of the thoracic spine, cervical spine and brain indicated the following: MRI of the thoracic spine showed multiple areas of abnormal signals predominantly in the inferior half of the thoracic spinal cord, compatible with areas of demyelination; MRI of the cervical spine showed multiple cord lesions, most important at C1-C2, compatible with demyelinating plaques and multiple sclerosis and severe left neural foraminal narrowing at C3-C4 related to disc osteophyte complex; MRI of the brain without contrast showed prominent periventricular white matter disease consistent with multiple sclerosis. Contrast enhancement to assess for acute plaque was recommended. Last week, on approximately 24-MAY-2010 the patient was diagnosed with Multiple sclerosis. The patient's multiple sclerosis persisted. The nurse practitioner did not believe there was a causal relationship. Their office had no other details since they are not the primary physician. The nurse practitioner contacted during the telephone follow-up could not supply the actual date of the event. Upon internal review, multiple sclerosis was considered to be an other important medical event. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 06/17/10. PCP for 04/5/10, 06/14/10. DX: MS, hypothyroidism, congenital adrenal hyperplasia. tx: steroids, methotrexate.

Other Meds: hormonal contraceptives; methotrexate

Lab Data: magnetic resonance, 03/04/10 The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: increased TSH, MRI abnormal.

History: The following information was obtained through follow-up and/or provided by the government. PMH: congenital adrenal hypoplasia. Allergies: PCN.

Prex Illness: Congenital adrenal hyperplasia; Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390309-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Jun-2010	08-Jun-2010	0	09-Jun-2010	09-Jun-2010	IN		11-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049CA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3088AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Loss of consciousness

Symptom Text: Vaccination administered at approx. 2:40pm. Pt. instructed to remain seated in waiting room while sibling was being vaccinated. At about 2:50pm, pt. passed-out while sitting in chair. Pt. slid between 2 chairs rolling on to her stomach and struck head either on chair or floor striking head along head-band just left of center top of head. Ice applied. Pt. was able to leave clinic at 3:20pm.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390314-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	09-Jun-2010	09-Jun-2010	0	09-Jun-2010	09-Jun-2010	MN		10-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Immediate post-injection reaction, Screaming

Symptom Text: Patient was injected with Gardasil Vaccine. I left the room and within 30 seconds, she was yelling help. I entered the clinic room and found her on the floor. She did not know how she got there. Within a few minutes she was feeling better.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **390327-1** **Related reports:** 390327-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	M	09-Jun-2010	09-Jun-2010	0	09-Jun-2010	10-Jun-2010	MI		10-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U3273BA		Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0245Z	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0298Z		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disorientation, Gaze palsy, Pallor, Tonic clonic movements

Symptom Text: Within minutes 2-3 client became pale, eyes rolled back, limp and disoriented. Clonic/tonic like activity. Client was disoriented for 3-4 minutes.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **390327-2** **Related reports:** 390327-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	M	09-Jun-2010	09-Jun-2010	0	22-Jun-2010	23-Jun-2010	MI	WAES1006USA01776	23-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0298Z	0	Unknown	Unknown	
	HEPA	MERCK & CO. INC.	0245Z		Unknown	Unknown	
	FLU	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Initial and follow up information has been received from a physician and a clinical coordinator concerning a 16 year old male patient with no known drug allergies, concurrent conditions or pertinent medical history who on 09-JUN-2010 was vaccinated with a 0.5 ml first dose of GARDASIL (lot number 665266/0298Z). The clinical coordinator reported that just prior to receiving GARDASIL the patient received a dose of VAQTA (lot number 667262/0245Z) and a dose of AFLURIA (manufacturer unknown) (lot number). There were no concomitant therapies (other than the mentioned vaccines). It was reported that the patient had not eaten before going to the office. The clinical coordinator reported that the patient experienced a seizure within 45 seconds of receiving the vaccination, the seizure lasted between 1 1/2 and 3 minutes, 911 was called. The patient was positioned and was given oxygen, no other treatment was needed. By the time the ambulance arrived the patient had fully recovered so a trip to the emergency room (ER) was not necessary. There were no plans for a neuro consult. It was reported that the patient wanted to receive the next dose. Upon internal review seizure was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **390335-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Jun-2010	09-Jun-2010	0	10-Jun-2010	10-Jun-2010	CA		10-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Feeling of body temperature change, Headache, Hyperhidrosis, Loss of consciousness, Pallor, Tinnitus

Symptom Text: Became white, profuse sweating, felt pressure in head like a tight band around head, ringing in ears, hot at first then cold, lost consciousness for about 30 seconds, body jerked twice.

Other Meds: None

Lab Data: None. Stayed with physician for 45 minutes afterward. Released to home. Continued to be very pale white for 2 hours and fatigued. Physician reported that they have this happen frequently when they administer Gardasil.

History: no

Prex Illness: No

Prex Vax Illns: None~ ()~~0.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390355-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Jun-2010	07-Jun-2010	0	10-Jun-2010	10-Jun-2010	KY		11-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1377Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vision blurred

Symptom Text: Pt. complained of blurred vision about 10 mins after injection of GARDASIL. Denied lightheadedness, dizziness or ringing in ears. This improved, then resolved by 25-40 min after administration of vx.

Other Meds: None

Lab Data: Mitral vision screen 20/20 & 20/40 with repeat of 20/20 each eye before discharge from office

History: NKA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **390380-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	09-Jun-2010	09-Jun-2010	0	10-Jun-2010	10-Jun-2010	CA		11-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1495Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Central nervous system stimulation, Depressed level of consciousness, Hyperhidrosis, Immediate post-injection reaction, Nausea, Syncope, Urinary incontinence, Vomiting

Symptom Text: Immediately after shot administered patient fainted, shook slightly, and urinated. Ammonia capsule had no effect on arousing patient. With stimulation, patient awakened, asked "what happened", and was diaphoretic. Subsequently was nauseaed and vomited several times. Patient has hx of syncope in past.

Other Meds: After return of consciousness, Zofran was given P.O. for nausea.

Lab Data: EKG performed - sinus arrhythmia; patient declined lab testing and IV placement. Left Against Medical Advice.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **390393-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Apr-2010	12-May-2010	23	10-Jun-2010	11-Jun-2010	--		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	2	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3057AA		Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anaemia, Body temperature increased, Burning sensation, Complex regional pain syndrome, Conversion disorder, Dysaesthesia, Dysarthria, Flat affect, Flushing, Hyperaesthesia, Livedo reticularis, Muscular weakness, Naevus flammeus, Neck pain, Neuropathy peripheral, Oedema peripheral, Pain in extremity, Paraesthesia, Temperature difference of extremities

Symptom Text: Burning dysesthesias in all extremities with flushing of arms and mottling of legs and changes in extremity temperature with increased skin temperature in arms and decreased in legs. The following information was obtained through follow-up and/or provided by the government. 06/11/10. Neurology consults 04/26/10-06/03/10. On 04/26/10, nevus flammeus L arm, chronic neck pain, acute onset of weakness of arms/legs, sensory changes with paresthesias. Pt On 05/12/10, Pt p/w paresthesias, neck pain, tingling of tongue, cheeks, hands and feet. On exam: hyperesthesias and decreased sensation of arms and legs. Assessment: complex regional pain syndrome (CRPS). On 06/03/10, Pt p/w progressive dysesthesias, chronic regional pain syndrome. Tx: nortriptyline, prednisone. Pt was admitted to hospital. 06/14/10. PCP 04/19/10-05/06/10. PCP routine visit 04/19/10 normal. On 04/28/10, Pt p/w neck pain, weakness and tingling hands and feet. DX: neuropathy, questionable etiology. Pt admitted to hospital 04/28/10-04/30/10 for neuropathy. DX: conversion disorder. Pt had flat affect. Pt continued with tingling, burning, stabbing pains in legs. 06/15/10. ER report, DC summary for 04/28/10-04/30/10. DX: conversion disorder, nevus flammeus L arm, anemia, chronic neck pain. Pt with slurred speech, neck pain, weakness and tingling hands and feet. 06/14/10. Pediatrics consult on 06/05/10. Pt admitted on 06/03/10 for pain management and rehabilitation evaluation. DX: (CRPS). Tx: biofeedback, acupuncture. Pt tolerated pain well. 06/30/10. DC summary for 06/03/10-06/11/10. DX: complex regional pain syndrome, s/p rehabilitation. Pt p/w pain, burning, tingling in BUE and BLE, sensitive to touch, sleepiness. Tx: Nortriptylin, prednisone. Pt received biofeedback, rehab, OT/PT.

Other Meds:

Lab Data: All testing negative...including MRIs, autoimmune & inflammatory markers. The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: Hgb 10.3 mg/dl (L), Iron 17 mcg/dl (L), MRI of spine;

History: None The following information was obtained through follow-up and/or provided by the government. PMH: abdominal pain, back pain, spontaneous R arm movements lasted 2-3 months and resolved spontaneously and was considered to be post/viral choreoathetosis. Allergies: none.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390399-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	10-Jun-2010	10-Jun-2010	0	10-Jun-2010	11-Jun-2010	AL		11-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MEN	SANOFI PASTEUR	U3069AA	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB431AA	0	Left arm	Unknown	
DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B053BB	5	Right arm	Unknown	
VARCEL	MERCK & CO. INC.	1772Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Syncope

Symptom Text: Brief fainting, jerking (once) with 5 minutes after shots. Treatment: cold compress, lying down, elevate feet.

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390409-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Jun-2010	09-Jun-2010	0	10-Jun-2010	11-Jun-2010	CA		23-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	SANOFI PASTEUR	U3076AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site pain, Syncope

Symptom Text: Patient here for immunizations; Gardasil and Meningococcal. LVN took patient to nurse's station to administer immunization. Nurse asked mother if patient was allergic to any medications, mom stated no. Before administering immunization, asked patient which arm she would prefer immz, mom stated both immz on left arm. Patient was standing when first immunization was administered (meningococcal). Patient stated she was fine. Proceeded to administer second immunization (Gardasil), patient stated "that one hurt it" and said she felt dizzy. Nurse and provider asked patient to have a seat. As he sat down, patient fainted; she was out for about 10 seconds. Once patient recovered, provider checked patients vitals; B/P 90/64. Patient stated was fine; patient left with parent.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390437-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Mar-2010	Unknown		11-Jun-2010	14-Jun-2010	--	WAES1006USA00605	14-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaphylactic reaction, Hypersensitivity, Injection site erythema, Injection site swelling, Nausea, Pain, Rash, Skin erosion, Skin lesion, Urticaria, Vomiting

Symptom Text: Information has been received from a physician assistant concerning a 13 year old female with no pertinent medical history, who on 17-MAR-2010 was vaccinated with the first dose of GARDSIL (IM, lot # 662299/1099Y). On 17-MAY-2010, she received her second dose (IM, lot #663558/0819Y). The physician assistant confirmed that the patient did not receive concomitant vaccinations when the first and second dose of GARDASIL were administered. After the first dose the patient developed "painful rash-like symptoms on her belly." For this rash, BACTRIM and steroids. The patient was treated approximately 6 weeks earlier with antibiotics and steroids for rash which patient's mother was attributing to dose 1 of GARDASIL. The rash resolved. On 31-MAY-2010, she reported to the emergency room with anaphylaxis, transient nausea/vomiting, site of injection redness/swelling, and painful rashes. It was reported that the patient's rash (unknown type) occurred 2 weeks following dose 2 of GARDASIL. Rash was evaluated in the ER after dose 2 and the term anaphylaxis was reported to the reporter from ER report. The patient was diagnosed with an allergic reaction and an urticarial reaction. The P.A. stated that there was post-allergic reaction, the patient developed lesions under her left arm. The patient had been treated with a 5 day course of steroids and topical ointment. Everything was resolved, except some painful "lesions" under the left arm. Rash was evaluated yesterday (02-JUN-2010) in office-"axilla skin erosion" was described by reporter. She was recovering. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390438-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-May-2010	12-May-2010	2	11-Jun-2010	14-Jun-2010	FR	WAES1006USA00679	14-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Arthralgia, Chills, Feeling abnormal

Symptom Text: Information has been received from a health authority (reference number ES-AGEMED-522625344) concerning a 16 year old female patient who on 10-MAY-2010 was vaccinated IM with a dose of GARDASIL (batch number and site not reported). It was reported that two days after vaccine administration, on 12-MAY-2010, the patient suffered unstable feeling, joint ache and chills. The patient recovered from these adverse events on 13-MAY-2010. The patient was in emergency ward for observation during 20 hours. The clinical tests and the vital constants were normal. The diagnosis was anxiety attack. Case reported as serious by the health authority with other medically important condition as criteria. To be noted, the health authority coded only unstable feeling, joint ache and chills. Other business partner numbers include: E2010-03458. Case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Vital sign, 12?May10, clinical tests and vital constants normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390439-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-Jun-2010	14-Jun-2010	--	WAES1006USA00690	14-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Influenza like illness, Loss of consciousness, Malaise, Pain, Visual impairment

Symptom Text: An online magazine reported that a consumer said that on an unspecified date her daughter was vaccinated with all 3 injections of GARDASIL and after each one she got sicker and sicker. At the time, the patient's mother had no idea that it was the shots doing it to her. After the first shot, she had flu like symptoms, would pass out and had seizures. The second shot left her with vision problems and a lot of pain. She was so sick to that she was hospitalized, but it was not possible to find what was wrong. The physician declared: "you have one sick daughter, but we don't know why". At the time of the report, the patient's outcome was unknown. It was unknown if the patient sought medical attention. Upon internal review, seizure was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **390440-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	30-Jun-2007		11-Jun-2010	14-Jun-2010	--	WAES1006USA00692	14-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Adrenal disorder, Arrhythmia, Bedridden, Convulsion, Decreased activity, Gastrointestinal disorder, Malaise, Migraine, Photophobia, Pupillary disorder, Sensory loss, Transient ischaemic attack, Vision blurred

Symptom Text: Information was received from an online magazine who reported that a consumer said that on an unspecified date her daughter was vaccinated with GARDASIL. It was reported that late June 2007, her daughter's life changed after GARDASIL. The patient went from a vibrant, active college student, to a bedridden, chronically ill, young woman with seizures, GI tract problems, constant migraines, blurred vision, abnormal pupil reaction, loss of feeling in both legs, heart arrhythmia, TIAs, eye sensitivity, exhausted adrenals and the list just kept growing. At the time of the report, the patient's outcome was unknown. It was unknown if the patient sought medical attention. Seizures was considered to be an other important medical event and bedridden was considered to be disabling. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **390443-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	01-Nov-2009		11-Jun-2010	14-Jun-2010	FR	WAES1006USA00675	14-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1400U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, General physical health deterioration, Headache, Nausea

Symptom Text: Information has been received from a health authority (reference number PEI2010010729) from a pediatrician concerning an 18 year old female with a history of migraine who in 2009 was vaccinated with the third dose of GARDASIL (batch # NH38400, lot # 1400U) IM. In Nov 2009, 14 days post-vaccination the patient developed nausea, abdominal pain, headache and severely reduced general condition. The patient was admitted to hospital for an unspecified time. After unspecified symptomatic treatment the patient recovered completely. Approximately 14 days after first (batch# NH 25730, lot#1695U) and second (batch# NH25390, lot# 1477U) vaccination with GARDASIL on unspecified dates the patient had developed nausea, abdominal pain and headache. Other business partner numbers included: E2010-03431. Case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Migraine

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390444-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	03-Jun-2010	03-Jun-2010	0	11-Jun-2010	14-Jun-2010	TX	WAES1006USA00759	14-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Fatigue, Underdose

Symptom Text: Information has been received from a physician and medical assistant concerning a female patient with seizures who on 03-JUN-2010 was vaccinated with a dose of GARDASIL in her arm which was not fully injected. The patient most likely got a drop, if that, of GARDASIL when all the sudden the patient had a seizure and the medical assistant pulled out the shot immediately. The patient had a seizure a couple of months ago while at a dentist office. The patient called a neurologist and her primary care physician to be seen. The patient felt exhausted after her seizure. The patient was in the process of trying to become pregnant. The office kept the vial of GARDASIL to show that most of the dose was still in the vial. At the time of the report, the patient's status was unknown. Upon internal review, "seizure" was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Convulsion

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390458-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Jun-2010	07-Jun-2010	0	11-Jun-2010	11-Jun-2010	ID		14-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	1	Right arm	Intramuscular	
	TD	SANOFI PASTEUR	U3005BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypoacusis, Nausea, Pallor

Symptom Text: Nauseated, hearing deficit, pale, light-headed, dizzy. Had patient lie down for 20 minutes.

Other Meds: None

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390513-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	11-Jun-2010	11-Jun-2010	0	11-Jun-2010	14-Jun-2010	TX		14-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1560Y		Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3131AA		Right arm	Intramuscular	
	MMR	MERCK & CO. INC.	1709Y	1	Left arm	Subcutaneously	
	IPV	SANOFI PASTEUR	D0413		Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1316Y		Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365AA		Right arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	1481Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Client c/o dizziness.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **390518-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Jun-2010	02-Jun-2010	0	11-Jun-2010	14-Jun-2010	OH		14-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0671Y	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3011AA	0	Left arm	Intramuscular	
IPV	SANOFI PASTEUR	D03042	0	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Nausea, Pallor

Symptom Text: Complained of dizziness, nausea. Became pale, diaphoretic. B/P 110/50, pulse 98. Positioned in supine position with leges elevated. Symptoms subsided after 40 minutes.

Other Meds:

Lab Data: N/A

History: Allergie to Cefzil. Asthmatic tendencies due to allergies

Prex Illness: no

Prex Vax Illns:

Vaers Id: **390569-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	23-Jan-2009	Unknown		11-Jun-2010	14-Jun-2010	KY	WAES0907USA01322B1	14-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Atrial septal defect, Cardiac murmur, Cough, Drug exposure during pregnancy, Nasal congestion, Patent ductus arteriosus, Rash

Symptom Text: Information has been received from a nurse practitioner and a consumer with no drug allergies and no pertinent medical history for GARDASIL, a Pregnancy Registry product. The baby's 24 year old mother did not have any previous pregnancies, pre-term deliveries, spontaneous abortions, elective terminations or fetal deaths. On 06-NOV-2008 the baby's mother was vaccinated with the first dose of GARDASIL (lot number unknown). On 23-JAN-2009 the baby's mother was vaccinated with the second dose of GARDASIL (lot number 661703/0651X). On 12-JUN-2009 the baby's mother was vaccinated with the third dose of GARDASIL (lot number 661703/0651X). On 16-FEB-2010, the baby's mother delivered the normal female baby with no congenital anomalies weighing 8 pounds, 7 ounces, length 20 inches. It was reported that the baby was stuck, so the patient had to have a C-section. The baby's mother had no concurrent medical conditions. On an unspecified date, the baby experienced heart murmur. At the time of the report, the patient's outcome was unknown. Follow-up information has been received via a medical record concerning the female baby with no known drug allergies who on 20-APR-2010 was vaccinated with the first dose of RECOMBIVAX HB (lot# 665622/1023Y) in her right thigh. Other concomitant vaccines administered on the same day included the first dose of DAPTACEL (manufacturer: Sanofi Pasteur) (lot# C3191AA) in the left thigh, the first dose of ACTHIB (manufacturer: Sanofi Pasteur) (lot# UF596AB) in the right thigh, the first dose of IPOL (manufacturer: Sanofi Pasteur) (lot#D0123) in the left thigh and the first dose of pneumococcal conj vaccine (unspecified) (manufacturer: Lederle) (lot#D93212) in the right thigh. On 24-FEB-2010, the 8 day old patient visited the office. her vital signs were within normal limits. She eats 2 to 4 ounces every four hours. She has bowel movements 1 to 2 times a day. At this visit the patient's patent ductus arteriosus was not audible. The patient was to follow up with cardiology as scheduled. On 05-MAR-201

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **390574-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	05-Nov-2008	Unknown		14-Jun-2010	15-Jun-2010	CA	WAES0903USA02927B1	15-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Birth mark, Circumcision, Congenital naevus, Drug exposure during pregnancy

Symptom Text: Information has been received from a Pediatrician via medical records concerning a male baby who was born to a 23 year old mother with allergy to anything in the "cillin family", PPD skin test positive and a history of caesarean section and tuberculosis exposure. It was reported that the mother had one previous pregnancy and one full term delivery. On 05-SEP-2008, 05-NOV-2008 and 16-MAR-2009 the mother was vaccinated with the first, second and third dose of GARDASIL, respectively (Lot # for the third dose: 661953/1130X). Her LMP was 16-FEB-2009. On approximately 17-MAR-2009, the mother experienced sharp pains located "4 inches below her belly button and 4 inches to the left of her belly button". She stated the pain might due to a previous caesarian section (see WAES #0903USA02927). On 16-NOV-2009, the mother delivered a normal, healthy male baby weighing 8 pounds, 6 ounces, length 21 inches. The mother had no complication and no infections or illnesses during pregnancy. The mother had no complication during labor/delivery. On an unspecified date the baby had a circumcision. On 12-APR-2010 the baby had a 4 month follow-up visit. It was reported that the baby was breast feeding 6 ounces every 2-3 hours and he was up 2 times at night. His height was 26 1/4 inches; weight was 18 pounds 6.5 ounces. Physical examination showed birth mark on his forehead and small Mongolian spot on his buttocks. The assessment was normal 4 month exam. On the same day the baby was vaccinated with the first dose of PREVNAR (lot #E38312) in the left, hepatitis B vaccine (Lot #AHBVB79CKA) in the left and PENTACEL (Lot# C355S7AA) in the right. Birth mark on his forehead and small Mongolian spot on his buttocks were considered to be congenital anomalies. Additional information has been requested. All available medical records will be provided upon request.

Other Meds: isoniazid; pyridoxine

Lab Data: Unknown

History: Caesarean section; TB exposure

Prex Illness: PPD skin test positive

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390577-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	U	03-Jan-2009	20-Jun-2009	168	14-Jun-2010	15-Jun-2010	--	WAES0904USA03151B1	15-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Talipes

Symptom Text: Information has been received from a certified nurse midwife concerning a prenatal baby whose mother, a 17 year old female, on 01-APR-2008, 17-OCT-2008 and 03-JAN-2009 was vaccinated with the first, second and third 0.5 ml IM dose of GARDASIL (lot # 658554/0928U, 660391/0063X, 661530/0575X) respectively. Concomitant therapy included prenatal vitamins (unspecified). Subsequently the patient's mother was pregnant. LMP was on 04-JAN-2009, estimated delivery date was 11-OCT-2009 (see WAES #0904USA03151). On 20-JUN-2009, the patient's mother had an anatomy survey sonogram which identified a left club foot. At the time of reporting, the outcome was unknown. Left club foot was considered to be congenital anomaly. The mother's experience has been captured in WAES 0904USA03151. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 06/20/09, left club foot

History: unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390578-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
-0.7	F	29-Jul-2009	29-Jul-2009	0	14-Jun-2010	15-Jun-2010	--	WAES0909USA01458B1	15-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cerebral ventricle dilatation, Drug exposure during pregnancy, Gastric disorder, Pericardial effusion, Thalassaemia alpha

Symptom Text: Information has been received from a medical assistant concerning a newborn female who's mother was vaccinated on 21-MAY-2009 and 29-JUL-2009 with a 0.5 ml first and a second dose (lot # 662300/0100Y) of GARDASIL. During pregnancy the patient was also exposed to YASMIN, CONCEPT and iron (unspecified) ("INTERJCA"). The patient experienced pericardial effusion, intracranial ventriculomegaly, stomach duodenum, possibly aneuploidy and alpha thalassemia trait (after baby born no abnormalities). The patient's outcome was unknown. The mother's experience has been captured in WAES # 0909USA01458. Pericardial effusion, intracranial ventriculomegaly, possibly aneuploidy and alpha thalassemia trait were considered to be congenital anomalies. Additional information has been requested.

Other Meds: CONCEPT; YASMIN; iron (unspecified)

Lab Data: Unknown

History:

Prex Illness: Anaemia; Sickle cell trait

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390579-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	F	01-Sep-2009	03-May-2010	244	14-Jun-2010	15-Jun-2010	--	WAES0910USA02157B1	15-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Intensive care, Jaundice, Sepsis, Weight gain poor

Symptom Text: Information has been received from a physician assistant, for GARDASIL, a Pregnancy Registry product, concerning a female 0 day old infant who on 01-SEP-2009 was vaccinated with a first dose of GARDASIL via transplacental administration. Concomitant therapy included vitamins (unspecified). On 03-MAY-2010 the infant experienced jaundice at birth and slow weight gain. On unspecified date, the infant was sent to NICU for r/o sepsis. At the time of the report, the infant recovered from jaundice at birth and slow weight gain. The outcome of sent to NICU for r/o sepsis was unknown. Additional information has been requested. The mother's experience has been captured in WAES0910USA02157.

Other Meds: Vitamins (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **390580-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		14-Jun-2010	15-Jun-2010	--	WAES1006USA00604	15-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a physician who heard of the experience second hand from a colleague (also a doctor) concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently the patient experienced muscle paralysis after the injection. It was unknown if the patient sought medical attention. At the time of the reporting, the patient's status was unknown. Upon internal review, the muscle paralysis was determined to be an other important medical event. All telephone attempts to obtain follow-up information have been unsuccessful. Additional information has been requested.

Other Meds: unknown

Lab Data: unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390581-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	31-Mar-2010	31-Mar-2010	0	14-Jun-2010	15-Jun-2010	FR	WAES1006USA00945	15-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353X	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Altered state of consciousness, Arrhythmia, Bradycardia, Hypertension, Hypotension, Hypotonia, Hypotonic-hyporesponsive episode, Neurogenic shock, Pallor, Paraesthesia, Pyrexia, Suffocation feeling, Vertigo

Symptom Text: Information has been received from a Health Authority (case n. 117752, local case n. IT253/10) concerning an 11 year old female patient with no medical history, no allergies, no fever and no other vaccines or drugs administered during the last 30 days prior to vaccination, who was vaccinated on 31-MAR-2010 at 15:00, with the first dose of GARDASIL (batch number NL44120, lot number 1353X) IM in the left deltoid. On the same day, five minutes following vaccination, she presented with vagal shock, altered level of consciousness (lipothymia) without loss of consciousness, tingling and a feeling of suffocation that resolved spontaneously. While being monitored at the vaccination clinic she also presented with alternating hypotensive and hypertensive episodes, bradycardia and arrhythmic pulse, pallor, fever 38 degrees celsius, hypotonia and hyporesponsivity. Due to the reoccurrence of the suffocation feeling, she was administered BENTELAN 4mg/2ml vial and saline solution IV. Due to onset of epigastric pain and vertigo emergencies were called and the patient was taken to the hospital at 16:15, she was discharged the same day at 19:00. The outcome is recovered on 31-MAR-2010. The agency coded transient alteration of awareness, arrhythmia, bradycardia, hypertension and hypotension. Other business partner numbers include: E2010-03467. The case is closed. No further information is available.

Other Meds: unknown

Lab Data: body temp, 31Mar10, 38 degrees C

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **390582-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Nov-2009	13-Jan-2010	56	14-Jun-2010	15-Jun-2010	FR	WAES1006USA00957	15-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1648U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Partial seizures

Symptom Text: Information has been received from a Health Authority (reference numbers PA20100179 and PA1000184) concerning a 19 year old female patient with a history of reactive arthritis who experienced generalized convulsions 8 weeks after she had received the first IM dose of GARDASIL (batch NH43700, lot 1648U) on 18-NOV-2009. On 13-JAN-2010, she experienced the first fit of generalized convulsions. On 27-JAN-2010, she received the second dose of GARDASIL (lot not reported). On 03-MAR-2010, the patient experienced the sixth generalized fit, and a seventh one on 04-MAR-2010. On 08-MAR-2010, she was seen by a neurologist. Corrective treatment with KEPPRA was implemented. Generalized seizures stopped. Were reported: dizzy spells and nocturnal partial seizures of the left upper limb, in the site of vaccination (dose not reported). As of 20-MAY-2010, the patient still experienced partial seizures of the left upper limb. She had corrective treatment with TRILEPTAL 300 morning and 300 mg evening, LAMICTAL 50 mg morning and 50 mg evening, and KEPPRA 500 mg evening. Tests found normal magnetic resonance imaging (MRI) and normal electroencephalography (EEG). Metabolic work-up was not performed. The patient recovered from generalized convulsions; at the time of reporting, she had not recovered from partial seizures and the outcome of dizzy spells was unknown. The Health authorities assessed the causal relationship between the reported reactions and vaccination with GARDASIL as 'doubtful' (C1 S1 T1) according to the method of assessment. The seriousness criterion reported by the Health authority was "other medically important condition." The Health authority coded convulsions generalized, partial seizures and dizzy spells. Other business partner numbers include: E2010-03487. No further information is available.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, normal; electroencephalography, normal

History: Arthritis reactive

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390601-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Jun-2010	11-Jun-2010	0	14-Jun-2010	14-Jun-2010	MO		14-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1773Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1497Y	2	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blister, Erythema, Pain, Pyrexia, Swelling

Symptom Text: PARENT CALLED STATING THAT CLIENT EXPIERENCED SWELLING/ REDNESS/ SORENESS. THE NEXT DAY CLIENT DEVELOPED FEVER OF 101 AND BLISTER ON THE OUTER AREA OF THE LEFT ARM. CLIENT WAS TAKEN TO ER BUT NO TREATMENT WAS GIVEN. CLIENT WILL SEE PMD TODAY.

Other Meds:

Lab Data: N/A

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390619-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Jun-2010	14-Jun-2010	0	14-Jun-2010	15-Jun-2010	OH		17-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0040Z	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Hyperhidrosis, Pallor

Symptom Text: Pt give injection 2 minutes later asked to sit felt lightheaded. Pt given cold rags with head between legs and started seizing. For approx 2 min talk pt through it and eventually came around. Pt very sweaty and no color.

Other Meds: LOESTRIN 24.

Lab Data:

History: None.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390632-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Sep-2008	22-Sep-2008	3	14-Jun-2010	15-Jun-2010	OH		15-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Fatigue

Symptom Text: Patient c/o vague fatigue and joint pain in her wrists especially while playing her flute. Pain increased significantly by 10/09/08. Now joint pain is so severe she can no longer play the flute, run, write for long periods, jump, perform any repetitive activities for very long. Numerous medications including Lyrica, Neurontin, Keppra, non-steroidal anti-inflammatories, Tylenol, Voltaren gel do not help. Ultram decreased pain a little-accupuncture tx made it easier to manage. Traditional physical and occupational therapy, and biofeedback hasn't helped.

Other Meds: none

Lab Data: MRI of wrist, cervical spine X-rays, sed rate, CBC, other blood work for signs of inflammation, Lyme ds, mono, arthritis-multiple physical exams all negative

History: none

Prex Illness: wrist pain of unknown cause

Prex Vax Illns: joint pain/vague fatigue~HPV (Gardasil)~1~17.17~Patient

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390636-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jun-2010	14-Jun-2010	0	14-Jun-2010	15-Jun-2010	ME		18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt. had fainting episode, lasting momentarily. Monitored and watched in office for 25 min.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **390656-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	09-Oct-2009		15-Jun-2010	16-Jun-2010	TX		16-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Blindness, Convulsion, Hypersensitivity, Paralysis, Tic

Symptom Text: GARDASIL-series of three injections alleged to prevent HPV/cervical cancer.....caused debilitating and non-treatable symptoms and side affects ongoing including seizure, convulsion, paralysis, loss of sight, hypersensitivity to foods, involuntary motor tics, etc.

Other Meds:

Lab Data: All initial tests including EEG, MRI, cat scan, chest x-ray, multiple blood tests reveal all no infection or abnormalities.

History: none

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390658-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	27-Apr-2009	30-Jul-2009	94	15-Jun-2010	16-Jun-2010	MD	WAES0907USA03082	16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood test, Breech delivery, Caesarean section, Drug exposure during pregnancy, Foetal disorder, Premature rupture of membranes, Ultrasound scan, Urinary tract infection

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 26 year old female with no pertinent medical history and no allergies who on 27-APR-2009 was vaccinated IM with the second 0.5ml dose of GARDASIL (lot# 661952/1129X). There was no concomitant medication. The patient discovered that she was pregnant during the GARDASIL series. At the time of reporting, it was unknown when the patient received her first dose of GARDASIL. No adverse effects reported. The patient sought medical attention through an office visit. Blood work-up and ultrasound were ordered. Results were not received at the time of reporting. The patient's last menstrual period (LMP) was reported as 21-MAY-2009. The estimated delivery date (EDD) would be on 25-FEB-2010. Follow up information has been received from a health professional indicated that the patient experienced urinary tract infection during pregnancy and was treated with MACROBID 100mg, which started on 30-JUL-2009 for 7 days. The patient got a shot of flu vaccine on 12-OCT-2009. The patient developed preterm premature rupture of membranes during pregnancy, and on 26-DEC-2009, 31 weeks from LMP, delivered an abnormal male infant (weight 3 pounds 15 ounces, apgar 3/7) (0907USA03082B1). During delivery, the baby was in a breech position and had to have a cesarean delivery. The infant had intraventricular bleed. At the time of the report, the patient's outcome was unknown. Upon internal review, breech delivery was determined to be an other important medical event. The baby's experience has been captured in WAES# 0907USA03082B1. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 5/21/2009)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390659-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	27-Apr-2009	26-Dec-2009	243	15-Jun-2010	16-Jun-2010	--	WAES0907USA03082B1	16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Apgar score abnormal, Breech presentation, Drug exposure during pregnancy, Intraventricular haemorrhage neonatal, Premature baby

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 26 year old female who on 27-APR-2009 was vaccinated IM with the second 0.5ml dose of GARDASIL (lot# 661952/1129X). There was no concomitant medication. The patient discovered that she was pregnant during the GARDASIL series. The patient's last menstrual period (LMP) was reported as 21-MAY-2009. The estimated delivery date (EDD) would be on 25-FEB-2010. On 26-DEC-2009, 31 weeks from LMP, the mother developed premature rupture of membranes. The infant was in the breech position so the mother had to have a Cesarean section to deliver the baby. The infant was reported to be abnormal with an intraventricular bleed. He weighed 3 pounds and 15 ounces. His Apgar score was 3/7. It was also reported that the mother experienced urinary tract infection during pregnancy and was treated with MACROBID 100mg, which started on 30-JUL-2009 for 7 days. The mother got a shot of flu vaccine on 12-OCT-2009. The mother developed preterm premature rupture of membranes during pregnancy. During delivery, the baby was in a breech position and then the mother had a cesarean. The infant had intraventricular bleed. At the time of the report, the baby's outcome was unknown. Upon internal review, intraventricular bleed and born at 31 weeks from LMP were considered to be other important medical events. The mother's experience has been captured in WAES# 0907USA03082. Additional information has been requested.

Other Meds: unknown

Lab Data: unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **390660-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-Jan-2009	06-Jan-2009	0	15-Jun-2010	16-Jun-2010	--	WAES1004USA03024	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Cervicitis, Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female patient who in January 2009, was vaccinated with the third dose of GARDASIL (Lot # not provided). It was reported that the patient was diagnosed with an abnormal pap smear. Both: low grade and high grade HPV were identified. No further details were given. At the time of the report the patient's status was not specified. Follow-up information was received from a health care professional via medical records, concerning the female patient with no illness at the time of vaccination and no known drug allergies who in 04-OCT-2007 was vaccinated with the first dose of GARDASIL, (Lot # 0560U), IM into the left deltoid, on 13-DEC-2007 was vaccinated with the second dose of GARDASIL (Lot # 655154/1210U), IM into the left deltoid and on 06-JAN-2009 was vaccinated with the third dose of GARDASIL (IM into the left deltoid. On 09-MAR-2010, a pap Smear test was performed which showed high grade squamous intraepithelial Lesion, mild dysplasia with HPV effect and chronic cervicitis. The squamous dysplasia extended into the endocervical glands. On 05-APR-2010, a colposcopy was performed which showed epithelial cell abnormality. A low grade squamous intraepithelial lesion (LSIL) was shown. At the time of the report, the outcome of the patient was unknown. High grade squamous intraepithelial Lesion and low grade squamous intraepithelial Lesion were considered to be an other important medical event per investigator. No further information is available.

Other Meds: Unknown

Lab Data: cervical smear, 03/09/10, abnormal: high grade and high grade HPV were identified; colposcopy, 04/05/10, low grade squamous intraepithelial Lesion

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390681-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Mar-2010	25-Mar-2010	0	15-Jun-2010	15-Jun-2010	NH		18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0315Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Overall numbness/parethesia, onset several hours after vaccine lasting through next day.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390684-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	M	08-Jun-2010	08-Jun-2010	0	15-Jun-2010	15-Jun-2010	IN		18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1317Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: 6/8/10 10:48 -Pt. received HPV #2 and TB PPD. 11:09 -Pt. and mother were checking out. Pt. with syncopal episode in hallway, landed on R side of face/forehead. Aroused shortly after with use of ammonia inhalant. Examined by MD, MD monitored pt. Pt. will be back in office on Fri 6-11-10 to have PPD read.

Other Meds: APLISOL; CLARITIN prn

Lab Data:

History: None Known

Prex Illness: None Known

Prex Vax Illns:

Vaers Id: **390696-1 (S)** **Related reports:** 390696-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-May-2009	28-Sep-2009	131	15-Jun-2010	16-Jun-2010	MO		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Anxiety, Back pain, Chest discomfort, Chest pain, Contusion, Dyspnoea, Headache, Muscle spasms, Nausea, Pain in extremity, Panic attack, Pleurisy, Pleuritic pain, Pulmonary embolism, Pyrexia

Symptom Text: Pain in legs and back after 15 days/30 days. Shortness of breath 45 days. Pulmonary Embolisms 45 days. Chest pains-45 days. 9 months treatment-DOVENOX and WARFARIN. The following information was obtained through follow-up and/or provided by the government. 6/17 to 6/21/10 Hospital records and discharge summaries received for dates of service 9/28/09 to 3/18/10. Final Dx: Bilateral pulmonary Emboli. Anxiety and Chest Pain, resolved. Presents to ED with a 1 wk. hx. of SOB with minimal exertion or even at rest. Also developed a pleuritic bilateral chest pain and chest tightness. Evaluated and found to have bilateral pulmonary emboli, admitted to the telemetry unit. Also c/o some cramping of the thighs and calves at times over the past few weeks. Also suffers from anxiety and panic attacks. Pt. has an IUD and started OCP"s 10 days prior to admission. Also on phentermine for weight loss. Started on Lovenox and Coumidin. Developed fever, nausea and headache. Notes bruising on abdomen and legs. Pt. medically stable for release on the date of discharge. 7/1/10 ED records and labs received for dates of service 9/28/09 to 10/19/09. Presents to the ED with chest pain under L breast and dyspnea. EKG shows normal sinus rhythm. Impression: Pleurisy, possibly a post embolus type pleurisy.

Other Meds: Depo provera

Lab Data: CAT scan - bilateral pulmonary embolisms The following information was obtained through follow-up and/or provided by the government. 6/17 to 6/21/10 Hospital records and discharge summaries received for dates of service 9/28/09 to 3/18/10.

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390696-2 (S)** **Related reports:** 390696-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-May-2009	28-Sep-2009	131	06-Aug-2010	09-Aug-2010	--	WAES1007USA01543	09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Back pain, Chest pain, Dyspnoea, Pain in extremity, Pulmonary embolism

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 22 year old female on 20-MAY-2010, was vaccinated with a second dose of GARDASIL (Lot number 661952/1129X). Concomitant therapy included DEPO-PROVERA. On 28-SEP-2009, the patient experienced pain in legs and back pain after 15 days/30 days. Shortness of breath 45 days. Pulmonary embolisms 45 days. Chest pains 45 days. A CT scan showed bilateral embolisms. The patient received 9 months of treatment with DOVE and warfarin. The listing indicated that one or more of the events required hospitalization, was considered to be immediately life-threatening. No further information is available. This was originally reported by a consumer. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The Evaluation and Research and was released. The VAERS ID # is 390696-1.

Other Meds: DEPO-PROVERA

Lab Data: Computed axial, bilateral pulmonary embolisms

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390700-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Jun-2010	10-Jun-2010	1	15-Jun-2010	15-Jun-2010	IA		18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3357BA	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Redness, swelling at injection site of MENACTRA. DEPO MEDROL 80mg IM given Rt vent. gluteal also that day.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390703-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Jul-2008	08-Jul-2008	-2	15-Jun-2010	15-Jun-2010	--		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Autoimmune disorder, Epstein-Barr virus infection, Menstruation irregular, Personality change, Swelling

Symptom Text: Adverse reaction to GARDASIL vaccine. 9 year old healthy college athlete has missed a year of school and been extremely ill with autoimmune diseases, chronic EBV, massive face and body swelling, personality change, menstrual change since receiving the second of 2 GARDASIL vaccines.

Other Meds:

Lab Data: hundreds of blood tests, labs, mri's. Most come back negative with exception of Hashimoto's/thyroid panel which is positive.

History: No pre-existing conditions. Healthy college cross country runner prior to GARDASIL.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390710-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	20-Apr-2010	20-Apr-2010	0	15-Jun-2010	15-Jun-2010	FL		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	08270	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea

Symptom Text: Pt w/ history of allergies - on BENADRYL - on TAMAZEPAM X 1 wk for depression - got GARDASIL - kept flat X 15 min - was ok on D/C - when got home - c/o "dizzy", light headed, nausea (4/20) cont. 4/21 with symptoms - went to ER - labs negative EEG negative per dad - 4/22 c/o headache but felt better.

Other Meds: BENADRYL; TAMAZEPAM

Lab Data: EEG negative; labs at ER (Records pending).

History: History of seizures; Migraine; Develop. delay

Prex Illness: Allergic rhinitis (mild)

Prex Vax Illns:

Vaers Id: 390712-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Nov-2008	14-Nov-2008	0	15-Jun-2010	16-Jun-2010	--		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Computerised tomogram normal, Confusional state, Convulsion, Disturbance in attention, Dyspnoea, Feeling abnormal, Hypoaesthesia, Muscle twitching, Syncope, Vision blurred

Symptom Text: GARDASIL....First shot only, seizures, fainting as many as 20 times a day, blurry vision at times, muscle twitches, numbness in legs and arms on and off, memory loss, trouble with concentration, brain fog and confused, trouble breathing at times, now can not have any citric acid.

Other Meds:

Lab Data: Many doctor visits, Jan. 3, 2010. E.R visit, because of seizure and could not sleep and shakiness feeling. They did blood work, urine test, EKG, Head scan, Chest scan, hooked up to heart monitor. All test came back normal.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **390713-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Jul-2007	24-Jul-2007	0	15-Jun-2010	16-Jun-2010	--		18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0187U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Back pain, Dizziness, Headache, Hypoaesthesia, Muscular weakness, Neck pain, Paraesthesia, Wheelchair user

Symptom Text: My healthy eighteen year old daughter received the GARDASIL vaccination in July, 2007. Immediately felt dizzy and had to lie down. The next week she mentioned that she had pain in her back and neck. Not knowing her symptoms were related to the GARDASIL vaccination, she had a second dosage in October, 2007. She went to the ER for a headache. She had numbness and tingling in her hands and arms, muscle weakness, and severe back pain. After many trips to the ER the neurology department - could not diagnose her. She had to use a wheelchair. A straight-A and once athletic student, she had to drop out of college due to her illness. Her EEGs were highly abnormal, including her evoked potential. We were sent to a clinic where they finally diagnosed her with fibromyalgia. The doctors didn't believe it was fibromyalgia and now her internal doctor feels it may have been due to the GARDASIL vaccine. Her doctor reported it to VAERS.

Other Meds:

Lab Data: EEG and Evoked Potential tests were abnormal. Autoimmune test was abnormal. Vitamin D levels were low.

History: No pre-existing conditions.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390723-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	03-Nov-2009	04-Nov-2009	1	15-Jun-2010	15-Jun-2010	MS		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Hypoaesthesia, Insomnia, Joint stiffness, Local swelling, Lymphadenopathy, Musculoskeletal stiffness, Oropharyngeal pain, Pain in extremity, Paraesthesia, Parotitis

Symptom Text: Patient states that the next day after vaccine administration she became fatigued. This resolved over a few days however several weeks later she had neck swelling which another MD diagnosed her with parotiditis and Rx antibiotics and Decadron. At the end of December she devleoped deep throat muscle pain and neck swelling. Strep throat swab negative. She was given another antibiotic. She then saw another MD who questioned MONO but she had had no fevers. He checked a CBC and WC was elevated and he prescribed another antibiotic. She then developed muscle and joint stiffness in her knees and shoulders and hips. An ENT MD saw her and a CBC was repeated with elevated white count and he saw lymphadenopathy. EBV blood test was positive. HE gave Decadron. She then received her second Gardasil vaccine on 1/10/2010. She then began having trouble sleeping along with her joint stiffness. She was prescribed Lortab. She then went to another MD who ordered arthritis labs (ANA, RF, ESR, TSH - all negative). White count normalized. He prescribed NSAID. She then started having numbness and tingling in her fingers and pain in her feet. No swelling, fevers, rash on exam. She did not get the third Gardasil vaccine.

Other Meds:

Lab Data:

History: none that patient was aware of

Prex Illness: none that patient is aware of

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390725-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Jun-2010	Unknown		15-Jun-2010	15-Jun-2010	CA		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0558X	0	Left arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	U3048AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered, No adverse event

Symptom Text: No adverse event. Expired HPV immunization given. Re-given 7 days later.

Other Meds: 0

Lab Data:

History: NO

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390727-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Jun-2010	15-Jun-2010	0	15-Jun-2010	16-Jun-2010	CA		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1539Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Fainted after receiving injection.

Other Meds:

Lab Data: none

History: asthma

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390732-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Jun-2010	04-Jun-2010	1	15-Jun-2010	16-Jun-2010	GA		16-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC586050AA		Left arm	Unknown	HEPA
PPV	MERCK & CO. INC.	1135Y		Left arm	Unknown	
MEN	SANOFI PASTEUR	U3360AA		Left arm	Unknown	
FLU	SANOFI PASTEUR	U3366AA		Right arm	Unknown	
HPV4	MERCK & CO. INC.	1332Y		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Patient described had a high fever for 4 days total. Treated at hospital on 6-4-10, noted administered TORADOL and Rx - Tx LEVAQUIN AB Tx 3 days.

Other Meds: Unknown

Lab Data: reported urine - on Tx for UTI via hospital

History: Unknown

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390733-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Jun-2010	08-Jun-2010	0	15-Jun-2010	16-Jun-2010	WV		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC528061BA	0	Left arm	Intramuscular	
	MEN	SANOFI PASTEUR	U3334AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1332Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Syncope immediately following vaccination of Tdap, MENACTRA, and GARDASIL. Episode only lasted few brief seconds and pt recovered spontaneously without any treatment. Pt was observed in clinic for 20 minutes after event and discharged home without further issues.

Other Meds: Multivitamin

Lab Data: None

History: None except scoliosis

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390742-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	10-Jun-2010	10-Jun-2010	0	15-Jun-2010	16-Jun-2010	MO		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	03312	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Cough, Dysphonia, Fatigue, Headache, Immediate post-injection reaction, Influenza like illness, Lacrimation increased, Nasal congestion, Oropharyngeal pain, Pain, Pyrexia

Symptom Text: Received 1st injection GARDASIL. C/o Flu-Like symptoms immediately. Fever/chills, achiness, watery eyes, cough, nasal congestion, headache, fatigue, sore throat, hoarseness.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390754-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Jun-2010	11-Jun-2010	1	16-Jun-2010	16-Jun-2010	IL		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Myalgia, Oropharyngeal pain, Pyrexia

Symptom Text: Severe headache, high fever (104.6) sore throat, myalgias.

Other Meds: Seasonique

Lab Data: CMP, CBC, Blood Cultures and CXR

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390779-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Jun-2010	Unknown		16-Jun-2010	16-Jun-2010	CA		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: No adverse event. Expired # 2 HPV immunization given. Re-given 7 days later.

Other Meds:

Lab Data: none

History: NO

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390781-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Jun-2010	Unknown		16-Jun-2010	16-Jun-2010	CA		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: No adverse event. Expired # 1 HPV immunization given. Re-given 7 days later.

Other Meds: none

Lab Data: none

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390782-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Jun-2010	Unknown		16-Jun-2010	16-Jun-2010	CA		16-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: No adverse event. Expired # 2 HPV immunization given. Re-given in 7 days.

Other Meds:

Lab Data: none

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390795-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2010	16-Jun-2010	MD	WAES0810USA04555	17-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Initial and follow-up information has been received from a physician and a medical assistant, concerning a female who on an unspecified date last year, in 2007 was vaccinated with the third dose of GARDASIL. It was reported that the patient experienced seizure. The patient was walking out of the office and went down. In follow-up information received from the nurse, she reported that the patient did not have a seizure. She passed out and recovered while in the office. This is one of two patients concerning the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	04-Nov-2008	04-Nov-2008	0	16-Jun-2010	16-Jun-2010	AZ	WAES0811USA00505	17-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Unknown	
	FLU	SANOFI PASTEUR	U2799AA	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Initial and follow up information has been received from a physician and a father concerning a 11 year old male student who on 04-NOV-2008 at 10:15 am, was vaccinated with the first dose of GARDASIL (Lot No 661764/0650X) in the left arm. Concomitant vaccination on 04-NOV-2008, included FLUZONE (Lot No U2799AA). The physician reported that inadvertently the GARDASIL was give to the patient instead of the patient's sister. At the time of the report no symptoms were reported. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **390801-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	27-Jun-2007		16-Jun-2010	16-Jun-2010	PA	WAES0906USA04454	17-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a physician concerning a 18 year old female patient who on 27-JUN-2007 and 25-JUL-2007 was vaccinated with a dose of GARDASIL (lot number, route and site not reported) which had been pre-drawn and stored in the refrigerator for up to one week. No adverse effect was reported except for "it always stings." It was unknown if the patient sought medical attention. The outcome was not reported. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390802-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.1	M	03-Sep-2008	03-Sep-2008	0	16-Jun-2010	16-Jun-2010	AL	WAES0809USA00476	03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U		Right leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Unevaluable event, Wrong drug administered

Symptom Text: Information has been received from a physician concerning a 5 weeks old male who on 03-SEP-2008 was inadvertently vaccinated with GARDASIL IM in the right thigh 0.5 ml (lot # 659182/1757U instead of HEP B (manufacturer unknown). This was a human error. There were no fever and no local reactions. No adverse experiences reported. The patient sought medical attention at the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **390803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Nov-2008	Unknown		16-Jun-2010	16-Jun-2010	--	WAES0901USA03933	18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a healthcare worker concerning a 17 year old female who on 20-NOV-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (Lot # 660612/0229X). Concomitant therapy included ADACEL, ALEVE and Multi-Vitamin. The patient developed hives on the left side of her face and neck after receiving her first dose of GARDASIL. The dose of GARDASIL was administered in the patient's left arm. At the time of reporting the patient was recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: ADACEL; ALEVE; vitamins (unspecified)

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **390804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		16-Jun-2010	16-Jun-2010	CA	WAES0801USA05473	17-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a medical assistant concerning a (approx.) 13 year old female who was not taking concomitant medications and was vaccinated (date, route and site not reported) with the 1st dose of GARDASIL (lot# not reported). On an unspecified date, the patient experienced abnormal periods. The patient's mother stated that after the 1st dose was received the patient periods became irregular. The patient did not receive medical attention via hospitalization nor an office visit. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Jun-2007	01-Aug-2007	33	16-Jun-2010	16-Jun-2010	CA	WAES0801USA00885	17-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a medical assistant concerning a 13 year old female who on 29-JUN-2007 was vaccinated (route and site not reported) with the 1st dose of the GARDASIL (lot# not reported). On 24-Aug-2007, the patient was vaccinated (route and site not reported) with the 2nd dose of the GARDASIL (lot # not reported). The mother of the patient stated that her daughter had had abnormal periods since the 2nd dose. The patient's periods were irregular from August to November. The patient's mother also said that her daughter was new to getting her period and was not sure if it was the vaccine or her body adjusting. The patient last period was November 2007. The patient did not receive medical attention via hospitalization nor an office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390806-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Jun-2010	16-Jun-2010	MO	WAES0802USA01175	17-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a healthcare professional, concerning a patient (age and gender not specified) who was vaccinated in the deltoid or thigh, on an unknown date with a dose of GARDASIL, and experienced pain, swelling and redness at the injection site. No further identifying patient details were available. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **390807-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Jul-2009	30-Jul-2009	0	15-Jun-2010	18-Jun-2010	--		25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Blindness transient, Convulsion, Dizziness, Fatigue, Headache, Hypoaesthesia, Ovarian cyst, Paraesthesia, Paralysis, Postural orthostatic tachycardia syndrome, Syncope

Symptom Text: My formerly healthy 15 yr. old daughter received her one and only dose of the GARDASIL vaccine on July 30, 2009. Since then, she has been plagued with headaches, fatigue, dizziness, numbness and tingling of the legs and feet, non-epileptic seizures, temporary paralysis/blindness, fainting, ovarian cysts, etc. She was hospitalised once and has been to the ER 5 times. She missed nearly the entire school year due to her adverse reaction to the vaccination. She has been evaluation by a psychologist and a psychiatrist both of whom state she is psychologically healthy and well-adjusted. She was recently diagnosed with POTS by a cardiologist. She is on numerous medications and cannot be left alone. I have since learned that there are thousands of other girls experiencing the same thing. If it's not the vaccine, what is it? Please take this vaccine off the market for further study before more innocent lives are compromised.

Other Meds:

Lab Data: EKG; video EEG; CAT scan; urinalysis; MRI; MRA; multiple blood work-ups

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390815-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	15-Jun-2010	15-Jun-2010	0	16-Jun-2010	18-Jun-2010	ND	ND1023	18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	1455Y		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1377Y	0	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Pallor

Symptom Text: GAVE A PATIENT A HBV#1 IN LEFT DELTOID, THEN GAVE HPV#1 IN RIGHT VASTUS LATERALIS, PT GOT WHITE, AND PASSED OUT. PT DID NOT FALL, NOR HIT HIS HEAD. PT WAS OUT FOR ABOUT 10 SECONDS.

Other Meds: MULTIVITAMIN

Lab Data: NA

History: NA

Prex Illness: NA- CAME IN FOR A SPORTS PHYSICAL

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390820-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	M	16-Jun-2010	16-Jun-2010	0	16-Jun-2010	18-Jun-2010	CA		18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3353AA		Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1657Y	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3077AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Patient felt dizzy after receiving vaccines. Administer ammonia inhalant. Felt better. Had patient wait 15 min. Felt fine and left.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390834-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jun-2010	16-Jun-2010	0	16-Jun-2010	18-Jun-2010	OH		01-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B042BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Pallor

Symptom Text: Pt. received BOOSTRIX and GARDASIL in RD. When pt. left exam room to schedule appt. for next inj. she felt lightheaded and dizzy. Became very pale and fell to the floor with support from Mom returned pt. to exam room. BP checked, 100/72. Pt. stayed in exam room for approx 30 min longer with no further episodes of dizziness.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390835-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	15-Jun-2010	15-Jun-2010	0	16-Jun-2010	18-Jun-2010	MN		28-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1657Y	1	Right arm	Subcutaneously	
TDAP	SANOFI PASTEUR	158AA	0	Left arm	Intramuscular	
IPV	SANOFI PASTEUR	0120	4	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB359BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: No adverse events. Child was identified as her sister so given 2 vaccinations intended for her sister. Follow up received states adverse event onset date/time: 6/15/10 6:00 PM.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390836-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-Jun-2010	15-Jun-2010	0	16-Jun-2010	18-Jun-2010	VA		18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysphagia, Dyspnoea, Nausea

Symptom Text: Received injection 1:00 pm. by 4:00 pm had difficulty breathing & slight problem swallowing. Became nauseated. No problems at injection site. Reported no problems with HPV4 #1 given 5-6-10. Was trying to make appointment to see MD.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390839-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Jun-2010	11-Jun-2010	1	16-Jun-2010	18-Jun-2010	CA		18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0298Z		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3078AA		Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB362BA		Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B055AB		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None stated.

Other Meds:

Lab Data: Focal cellulitis only

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **390845-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	M	16-Dec-2008	04-Sep-2009	262	17-Jun-2010	18-Jun-2010	MD	WAES0903USA03210B1	18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Congenital anomaly, Congenital tongue anomaly, Cough, Dacryocystitis, Dacryostenosis congenital, Drug exposure during pregnancy, Ear congestion, Eye discharge, Feeding disorder neonatal, General physical condition abnormal, Jaundice neonatal, Nasal congestion

Symptom Text: Information has been received from a physician via medical records concerning a 3 day old infant who was born from a 26 year old female patient with no pertinent medical history and no known allergies, who on 28-JUL-2008 was vaccinated intramuscularly with 0.5 ml of the first dose of GARDASIL, the second dose on 22-SEP-2008 and the third dose on 16-DEC-2008 and conceived 1 week later after the third dose. The patient was seen on 18-MAR-2009 at the office and an ultrasound confirmed that the patient's gestation was 15 weeks and 2 days. On 02-SEP-2009, the patient was delivered by normal vaginal delivery at full term; weight 6 lb 1 oz, 20.5 inches, and head circumference 13 cm. On 04-SEP-2009, the patient had a short sublingual frenulum that was clipped. It was reported that on 05-SEP-2009, the patient was seen and the physical examination was normal except for abnormal appearance (jaundice). The physician recommended to watch the jaundice and to expose the patient to sunlight. The patient was diagnosed with neonatal jaundice and newborn feeding problems. On 17-SEP-2009, the patient was seen again in the office and the physical examination was normal except for an yellow drainage from left eye with no hyperemia, external ears and nose were congested, and cough. The patient was placed on erythromycin ointment to treat the eye. The patient was diagnosed with acute dacryocystitis and blocked tear duct/dacrostenosis. The patient was treated with erythromycin ophthalmic ointment, massage and cleaning. On an office visit on 05-OCT-2009, the patient was seen again and the physical examination was normal. The patient's weight was 9 pounds and 5 ounces (34% ile), height was 22.3 inches and head circumference was 36.8cm. Short sublingual frenulum and neonatal jaundice were considered to be congenital anomalies. The mother's experience is captured in WAES 0903USA03210B1. No further information is available.

Other Meds: unknown

Lab Data: unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **390846-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	14-Apr-2009	Unknown		17-Jun-2010	18-Jun-2010	--	WAES0905USA03365B1	18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ankyloglossia congenital, Circumcision, Drug exposure during pregnancy, Laboratory test normal, Rash neonatal

Symptom Text: Information has been received from a certified nurse midwife via pediatric medical records concerning an infant who was born from a 25 year old female with no pertinent medical history and no drug reactions or allergies who on 09-JAN-2009 was vaccinated with a first dose of GARDASIL (Lot # 660616/0570X) 0.5mL, intramuscularly. On 14-APR-2009 she received second dose of GARDASIL (Lot # 661678/0904X, which was valid for MMR II) 0.5ml, intramuscularly. Concomitant medication included vitamins. The patient's mother became pregnant. The patient's mother last menstrual period was on 17-APR-2009. Estimated date of delivery was 22-JAN-2010. It was reported that the patient's baby was born on 18-JAN-2010 at 7:41, weighing 3042g. The patient's mother was 39 weeks from her LMP. It was reported that the baby had a normal development and the review of systems was within normal limits, except for a newborn rash and a tongue tie. The baby's circumcision was healing well. It was also reported that the baby was tongue tied. The plan was to give ambulatory guidance. Laboratory tests performed were normal. Tongue tie was considered to be a congenital anomaly. The mother's experience is captured in WAES 0905USA03365. No further information is available. All available medical records will be provided upon request.

Other Meds: vitamins (unspecified)

Lab Data: unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 390847-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Nov-2008	01-Jan-2009	52	17-Jun-2010	18-Jun-2010	FR	WAES1006USA01828	18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Back pain, Fibromyalgia, Headache, Impaired work ability, Muscular weakness, Musculoskeletal pain, Myalgia, Pain, Pain in extremity, Vaccination complication

Symptom Text: Information has been received from a Health Authority on 09-JUN-2010 under reference 2010-01497. A 15 year old female patient received was vaccinated on the 10-NOV-2008 a first dose of GARDASIL (0.5 mL, batch # and site of administration not reported) via intramuscular route. The patient received the second dose of GARDASIL on 19-JAN-2009 and the third dose on 12-JUN-2009. In January 2009, she developed lumbar back pain for the first time. In the summer of 2009, she also developed shoulder pain with exacerbation and spread of the pain to the upper and lower limbs. The symptoms ultimately converged into a generalised pain syndrome with muscle pain, muscle weakness and headache. The patient was admitted to hospital for further examinations. No cause of the symptoms was found (rheumatological and neurological diagnostic investigations were negative, bony pathology of the cervical spine, arm and thigh musculature were unremarkable on ultrasound), so a relationship with the HPV vaccination was suspected. Certain symptoms of fibromyalgia were present, although clear indications of dermatomyositis and pressure points associated with fibromyalgia were negative. Therefore, fibromyalgia can neither be ruled out nor confirmed and remained a diagnosis to be excluded. The girl was otherwise healthy and was not taking any other medicines. For the symptomatic treatment of the pain in her thighs, the patient was treated with LIORESAL for muscle relaxation in November 2009 and SAROTEN RETARD leading to a slight improvement of the symptoms. Physiotherapy and acupuncture were unsuccessful, psychological care to help cope with the continuing pain situation was initiated. Outcome: The patient had not recovered and had sequelae including pain-induced termination of training in the public healthcare sector, currently unemployed, no more sports. Sender's comment: According to the agency, arthralgia and myalgia and headache on GARDASIL were listed as possible ADRS. The agency gives further details on this from the respective clinical stu

Other Meds: unknown

Lab Data: ultrasound, bony pathology of the cervical spine, arm and thigh musculature were unremarkable; neurological examination, negative; rheumatological and neurological diagnostic investigations were negative

History: none

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390868-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Oct-2009	Unknown		17-Jun-2010	18-Jun-2010	NC		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope after injection. Vital signs monitored for 30 min, pt stable. No other reactions noted.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390875-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Mar-2010	29-Mar-2010	0	17-Jun-2010	18-Jun-2010	NC		18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1480Y	0	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope after leaving office.

Other Meds: Ortho Tri-Cyclen

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **390878-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jun-2010	16-Jun-2010	0	17-Jun-2010	18-Jun-2010	KS		18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3357BA		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Cold sweat, Dyskinesia, Dyspnoea, Gaze palsy, Headache, Mydriasis, Pallor, Syncope, Unresponsive to stimuli

Symptom Text: Syncope, paleness, clammy skin, dilated pupils, jerky movements, clenched fist and jaws, unable to respond to verbal commands or questions, eyes fixed. Taken by wheelchair to be seen by on-call physician. Patient laid down, BP and pulse taken. Sips of water given once verbally responding appropriately. Observed by nursing. Assessed by Dr. and discharged home. Taken to car via wheelchair. Patient more alert and talking. Complaining of mild headache. Returned to clinic at 3:00 PM on same day with c/o shortness of breath and chest pressure. Assessed by Dr. See test results below.

Other Meds: None

Lab Data: SaO2=98% at rest; 93% when walking; Chest x-ray normal; EKG normal; CBC and BMP normal.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **390881-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jun-2010	16-Jun-2010	0	17-Jun-2010	18-Jun-2010	FL		03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3097AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB417AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Incoherent, Loss of consciousness, Nausea, Neurological examination normal, Presyncope, Staring, Syncope, Tunnel vision

Symptom Text: Mom states daughter had a seizure, was convulsing and incoherent. Mom took daughter to ER where tests were run to include a CAT scan. All tests were negative. Daughter became coherent after one hour of the event. Daughter is doing well now. Next week is scheduled for an MRI and EEG and then will see the neurologist. The following information was obtained through follow-up and/or provided by the government. 6/29/10 ED records received for date of service 6/16/10. Dx: Seizure. Pt. received immunizations. On the way home in the car c/o nausea, then described having tunnel vision followed by passing out. Mom observed flexing of arms in a rhythmic fashion along with head nodding while staring blankly, all sx. lasting about 3 minutes. Afterward patient was confused for about one hour. Presented to ED in NAD. VSS. CT of head normal. F/u EEG and MRI scheduled as well as appt. with neurology. Pt. discharged to home. 7/30/10 Neurology consult received for dates of service 7/14/10. Dx: Vasovagal syncopal attack. Neurological exam normal. EEG and MRI normal. Vasovagal syncopal attack diagnosed. To follow up with neurology only if necessary.

Other Meds: none

Lab Data: blood work, urine, CAT scan negative results The following information was obtained through follow-up and/or provided by the government. 7/30/10 Neurology consult received for dates of service 7/14/10. EEG-NL. MRI-NL.

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390884-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	21-Dec-2009	28-Dec-2009	7	17-Jun-2010	18-Jun-2010	PA		18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Chills, Costochondritis, Drug exposure before pregnancy, Dyspnoea, Fatigue, Headache, Infectious mononucleosis, Injection site rash, Malaise, Musculoskeletal chest pain, Oropharyngeal pain, Pain, Pyrexia, Rash, Rhinorrhoea, Vision blurred

Symptom Text: Having trouble breathing, severe pain in ribs, went to ER on 12/31 diagnosed with costochondritis. Within 30 days of vaccine got pregnant, ended up miscarrying. 3rd vaccine on April 21, 2010 sick ever since. Fever, aches, chills, sore throat, runny nose, mucus, extreme fatigue, headaches, blurred vision, rash on arm, did get rash at injection site with 3rd vaccine but that went away within 3 days. Went to Dr. end of May 2010 thought I had strep, antibiotics did nothing. Went back June 9, 2010, diagnosed with a possible ear infection and given antibiotics. Tested for Mono which came back positive.

Other Meds: Birth Control

Lab Data: Blood work came back normal except mono on 6/14/10, ER diagnosed with costochondritis in December 2009.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390914-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	20-Nov-2007	22-Jan-2008	63	17-Jun-2010	18-Jun-2010	TX		18-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1209U	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthropathy, Fatigue, Joint swelling, Oedema peripheral, Vaginitis bacterial

Symptom Text: bacterium vaginosum 01/22/2008 exhaustion 06/2008. Foot and turning head trouble 06/2008. left foot and left knee swelling with heat 09/2008. 11/2008 bacteria vaginosum and 3rd shot and spread to rest of joints. Treated with steroids, methotrexate for a year, anti inflammatories for a year. 06/2009 started remicade.

Other Meds:

Lab Data: I am positive for the HLA-B27 genetic marker for autoimmune problems. I have autoimmune arthritis which affects joints and organs, and ankylosing spondylitis which will only show up on an xray in about ten years.

History: none

Prex Illness: none

Prex Vax Illns: arthritis~HPV (Gardasil)~2~21.00~Patient|arthritis~HPV (Gardasil)~3~22.00~Patient

Vaers Id: **390920-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Jun-2010	16-Jun-2010	0	17-Jun-2010	18-Jun-2010	OR		21-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1771Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0318Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Swelling, Tenderness

Symptom Text: Local swelling about 2 inches in diameter mildly tender. No redness, no fever or streaking.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **390930-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Jun-2010	14-Jun-2010	0	18-Jun-2010	21-Jun-2010	FR	WAES1006MYS00037	16-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician concerning a female (in her late teens) who on 14-JUN-2010, at approximately 1pm, was vaccinated with the first dose of GARDASIL. On 14-JUN-2010, immediately after vaccination, the patient experienced fits and fainted. The physician allowed the patient to rest and subsequently, the patient recovered from fits and fainted. The patient has no history of fits and the mother said that the daughter had no issue with other vaccinations. At the same time that the patient was vaccinated, her two other sisters also came for the vaccination with GARDASIL. The "first sister vaccinated was ok". The patient was the second to be vaccinated. No information was provided concerning the third sister. Causality is unknown, but the physician thinks that it could be because the patient did not eat before coming for the vaccination. Upon internal review, fits was considered as an important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **390931-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	U	Unknown	Unknown		18-Jun-2010	21-Jun-2010	FR	WAES1006PHL00016	21-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning 13 year old patient who was vaccinated with all three doses of GARDASIL. Subsequently the patient experienced seizure six months after the last dose was given. The physician noted that the patient had no history of seizures or any medical condition which may have predisposed the patient to the seizure. Upon internal medical review, seizure was considered an important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **390962-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Jun-2010	16-Jun-2010	2	18-Jun-2010	18-Jun-2010	FL		21-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1480Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Pain, redness and swelling at injection site.

Other Meds: LoEstrin Fe

Lab Data: none

History: none

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391002-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Jun-2010	16-Jun-2010	0	19-Jun-2010	21-Jun-2010	CA		21-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash erythematous, Rash macular, Rash pruritic

Symptom Text: RED, ITCHY, BLOTCHY RASH SPREAD FROM CHEST TO FACE. DENIES ANY SOB.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391010-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	07-Apr-2008	24-Jul-2008	108	20-Jun-2010	21-Jun-2010	NC		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Abdominal pain, Anaemia, Balance disorder, Blood potassium increased, Chills, Complicated migraine, Confusional state, Constipation, Diarrhoea, Dizziness, Dysphemia, Flank pain, Gait disturbance, Headache, Hemiplegia, Hypertension, Hypoaesthesia, Lethargy, Migraine, Muscular weakness, Oedema peripheral, Paraesthesia, Postural orthostatic tachycardia syndrome, Syncope, Vision blurred, Vomiting

Symptom Text: Blurred vision, fainting, paralysis on left side, numbness, tingling, lethargic, stuttering, headache, constipation, abdominal pain. The following information was obtained through follow-up and/or provided by the government. PCP, ED records received 6/21/10. Service dates 1/26/07 to 10/28/08. Assessment: Possible migraine. 7/24/08 - Last week diminished vision, now legs and (L) arm numb, weak. 7/24/08 - Patient presents to ED with weakness of left upper extremity, left lower extremity, difficulty walking. Off balance, paresthesias of left upper and lower extremity. In no acute distress. Symptoms almost resolved after motrin administered. 8/7/08 - (R) side pain, vomiting and diarrhea. 10/28/08 - Patient c/o (L) flank pain and vomiting. 6/23, 6/25, & 6/28/10 Neurology and PCP records received for dates of service 9/24/08 to 6/17/10 Dx: Postural Orthostatic Tachycardia Syndrome. Anemia. Dizziness. Fainting. Hypertension. Migraine HA. Stroke Syndrome. Presents for evaluation of an episode of numbness affecting the L side of her body, and weakness to the extent of being unable to walk. Recently pt. was at work and developed numbness, went to ED where she experienced confusion and was diagnosed with complicated migraine. On another occasion pt. had tingling in the neck "like a cold chill." BP was high in the ED at 130/110. CBC revealed mild anemia. Had a transient episode of leg swelling which resolved spontaneously. Also has syncopal events lasting 15 to 20 seconds, preceeded by dizziness, lightheadedness and balance problems and followed by HA's. Dx of POTS made by tilt table.

Other Meds: Dose 1 Gardasil 1266U IM LA 12/12/07 Dose 3 Gardasil 0843X IM LA 10/09/08

Lab Data: Numerous CT scans and MRI's, labs, and test. The following information was obtained through follow-up and/or provided by the government. LABS and DIAGNOSTICS: CBC - WBC 12.1 K/cmm (H) HGB 11.8 g/dL (L) HCT 35.6% (L) MCH 26.1 pg (L) Lymphocy

History: The following information was obtained through follow-up and/or provided by the government. PMH: Biscuspid aortic valve problem. Penicillin allergy. Wisdom teeth removed. 1/26/07 - Patient "passed out" last night. Told to call neurologist. 6/23, 6/25, & 6/28/10 Neurology and PCP records received for dates of service 9/24/08 to 6/17/10 PMH: Amoxicillin allergy.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391042-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-May-2010	11-May-2010	9	21-Jun-2010	22-Jun-2010	FR	WAES1006USA01567	22-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0777X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood test normal, Eye pain, Headache, Visual acuity reduced

Symptom Text: Information has been received from a pharmacist concerning a 17 year old female who on 20-MAR-2010 was vaccinated with the first dose of GARDASIL (expiry APR-2011). On 02-MAY-2010 the patient was vaccinated with the second dose of GARDASIL (batch # NJ35160 lot 0777X, route and site not reported). The patient had no medical history, was described as sporty and resistant to pain. She had no concomitant treatment. The patient experienced reduced visual acuity and frontal headache after she had received the second dose of GARDASIL. On 11-MAY-2010 9 days after vaccination she noticed a sudden decrease in her visual acuity. On 12-MAY-2010, the ophthalmologist confirmed a decrease by 2/10 of the right eye's acuity. On 14-MAY-2010 the patient developed daily bouts of frontal headaches, the duration of which was unknown. Headaches were located in the forehead, around the eyes and "in" the eyes. She received corrective treatment with analgesics. Brain MRI and CT scan (dates not specified) were normal. Visual evoked potentials: marked bilateral extension of P-wave, from 100 to 120 msec. Routine blood work-up was normal. According to the neurologist and the ophthalmologist, considering the VEP, it was not a manifestation due to fatigue. No diagnosis was established. At the time of reporting, symptoms persisted. The patient was due to consult the neurologist on 14-JUN-2010. Upon internal review the case was considered medically significant. Other business partner numbers included: E2010-03632. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, brain: normal; computed axial tomography, normal; visual evoked potential, bilateral extension of P-wave from 100 to 120 msec

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391043-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		21-Jun-2010	22-Jun-2010	IL	WAES1006USA01570	22-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood test, Facial bones fracture, Fall, Loss of consciousness

Symptom Text: Information has been received from a physician, via an Agency (manufacturer # not reported), concerning a 16 year old female patient who was vaccinated with a dose of GARDASIL (date not reported). This report was part of a post-marketing surveillance program. Subsequently the patient passed out after administration and broke nose after falling. The event required a visit to the emergency room. Diagnostic tests carried out to diagnose the AE were blood work and blood pressure (results not reported). The patient recovered with sequelae. It was reported that therapy with GARDASIL was discontinued and that the events diminished after stopping therapy. The reporting investigator felt that passes out and broke nose were related to study therapy. Upon internal review it was considered that passes out and broke nose were other important medical events because the reporting investigator reported it as serious and no serious criteria were reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 391047-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Apr-2010	19-Apr-2010	0	21-Jun-2010	22-Jun-2010	FR	WAES1005USA00697	22-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353X	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Bed rest, Coxsackie virus test, Dehydration, Echovirus test, Electroencephalogram normal, Enterovirus test, Fundoscopy normal, Headache, Human papilloma virus test, Intracranial hypotension, Lumbar puncture, Nasal turbinate abnormality, Nasal turbinate hypertrophy, Pain, Post lumbar puncture syndrome, Sensation of pressure, Vomiting

Symptom Text: Case received from Health Authority on 04-MAY-2010 (case n. 116192) through SPMSD (local case n. IT203/10). An 11 year old female on 19-APR-2010 was vaccinated with the second dose of GARDASIL (IM, batch # NL44120, lot # 1353X). On the same day the patient was presented with significant headache not responding to treatment with analgesics. One week after onset of symptoms the patient was hospitalized. A brain MRI, head CT scan and CSF exam were performed and were all negative. The patient was discharged and recovered on 03-MAY-2010. The case is closed. Follow up information received from HA on 03-JUN-2010: The patient was admitted to hospital on 26-APR-2010 because of headache. She had received GARDASIL on 19-APR-2010 and the same evening the patient was presented with pulsating temporal headache not preventing the patient from sleep but precluding her daily activities. A recent ophthalmic consultation had excluded visual problems. Investigations performed on 23-APR-2010 (EEG), 24-APR-2010 (brain MRI, CBC, and C-reactive protein) were all within normal range. Upon admission, the patient was in good general conditions, regular vital signs, regular objective and neurological examination. Pain to pressure on the frontal and maxillary areas. Investigations performed during admission: neurological consultation, negative. ENT consultation no certain signs of acute sinusitis, advised facial CT scan which showed hypotrophy of the left inferior turbinate and modest hypertrophy of the right inferior turbinate with the mucosa touching in certain spots the mucosa of nasal fossa. Due to the headache persistence, on 27-APR-2010, a rachicentesis was performed, chemical analysis negative. Result not available for viral testing for HPV, enterovirus, neurotropic echovirus and coxsackievirus A and B. On 29-APR-2010, the patient's condition worsened the headaches forced her to lay in bed and worsened with vomiting if she assumed the seating position. A fundus oculi was performed and was normal. The patient was reassessed by the neur

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, ??Apr?10, brain MRI, negative; Head computed axial tomography, ??Apr?10, negative; Electroencephalography, 23Apr10, normal; Magnetic resonance imaging, 24Apr10, brain MRI, normal; Diagnostic laboratory test, 27Ap

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391055-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Jun-2010	18-Jun-2010	0	21-Jun-2010	21-Jun-2010	IN		21-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3064AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52BO45BA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Patient fainted within a few minutes of receiving vaccinations. Patient regained consciousness within about a minute of fainting.

Other Meds:

Lab Data:

History: no

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391077-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Jun-2010	15-Jun-2010	0	21-Jun-2010	21-Jun-2010	VT		22-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1411X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1333Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: GARDASIL & VARICELLA vaccine given. Pt alert, appropriate. Escorted to hall. Pt had syncopal episode, attended & examined by PA. VSS.

Other Meds:

Lab Data: T : 98.8; HR, 76; FSBS, 93; BP, 128/78; RR, 16

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **391089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	11-Jun-2010	11-Jun-2010	0	21-Jun-2010	21-Jun-2010	PR		22-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0027	1	Right arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B041CA	0	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U3080AA	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	1498Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Nausea, Syncope, Vomiting

Symptom Text: Sudden onset of dizziness, nausea, vomit & syncope sensation approx 20-30 min. after vaccination of HPV, MCV, DTP, VARIVAX.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 391115-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Jun-2010	19-Jun-2010	0	21-Jun-2010	22-Jun-2010	CA		22-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Pyrexia, Vomiting

Symptom Text: Patient felt dizzy right after vaccination. Patient stayed for 15 minutes then left. About 7 hours post vaccination patient developed fever and vomiting. Patietnt followed up on 6/21/10 still with on and off fever. Temp 101.6 in the clinic and still vomited 1x that day with episodes of dizziness.

Other Meds: Nystatin cream

Lab Data: None

History: Monilial Dermatitis

Prex Illness: No

Prex Vax Illns:

Vaers Id: **391118-1** **Related reports:** 391118-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Jun-2010	17-Jun-2010	0	21-Jun-2010	22-Jun-2010	MO		22-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Fatigue, Headache, Immediate post-injection reaction, Loss of consciousness, Nausea

Symptom Text: Shot given, passed out and had seizure, afterwards severe headache, nausea, fatigue, dizziness.

Other Meds:

Lab Data: Nothing yet still having symptoms, just treating the symptoms.

History: none

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391118-2** **Related reports:** 391118-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	16-Jun-2010	16-Jun-2010	0	25-Jun-2010	25-Jun-2010	MO		28-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Asthenia, Convulsion, Crying, Dizziness, Dyspnoea, Fatigue, Headache, Musculoskeletal stiffness, Nausea, Pallor, Posture abnormal, Tremor, Unresponsive to stimuli

Symptom Text: Approx 5 minutes after the vaccination client reported being dizzy. Approx. 1 minute after she said she was dizzy she then stated she was going to pass out. She then almost immediately went unresponsive and slumped over. She remainded unresponsive for approx. 2 minutes and also stiffened out her body and had seizure like tremors all within that 2 minute time period. Client then responded to me after this 2 minute time period and started to cry. Lips were ashen grey and she stated she was going to throw up, was extremely exhausted and had a massive headache. Client never did throw up but was extremely nauseated and continued to complain of a headache. She recovered moderately well in our office. Significant other then came to pick her up and take her home. I called client back on 6/17/10 to check on her and she stated she was having shortness of breath, still nauseated, headache, dizziness, no energy, and had taken Benadryl the night before to help sleep. Encouraged her to follow up with her dr. I spoke with client again on 6/18/2010 and she said she had no more shortness of breath but did go see her chiropractor to get "detoxified". She did report still having stomach upset and feeling tired but did feel better. I then called her on 6/22/10 and she reported still being sick to her stomach and having to take rest periods at work and having headaches.

Other Meds: none known

Lab Data: none

History: none known

Prex Illness: Client states having a "sinus headache"

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391120-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Jun-2010	11-Jun-2010	0	21-Jun-2010	22-Jun-2010	WA		22-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	C3351AA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3015AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	1537Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Pruritus, Urticaria

Symptom Text: The patient received the 4 vaccines listed below on 6-11-10. On 6-16-10 the mother called in and reported patient had itchy hands and feet the evening on 6-11-10. On 6-12-10 patient had swollen hands and feet and hives on trunk. Went away with BENADRYL. At time of conversation s/s had resolved.

Other Meds: Ortho-Tri Cyclen Lo

Lab Data: None

History: Allergy to PCN and Sulfa

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391134-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Jun-2010	22-Jun-2010	0	22-Jun-2010	22-Jun-2010	PA		23-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope within 10-15 min of administration of HPV vaccine #2.

Other Meds:

Lab Data: None BP fine post syncope = 122/80

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391139-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Jun-2010	Unknown		22-Jun-2010	22-Jun-2010	AZ		22-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B04BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0299Z	0	Left arm	Intramuscular	
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	027011	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Fainted immediately after vaccine administration.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391148-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Jun-2010	10-Jun-2010	0	22-Jun-2010	22-Jun-2010	OH		23-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049AA	5	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0847X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3056AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope, Tonic clonic movements

Symptom Text: Patient was given BOOSTRIX to rt deltoid first; GARDASIL Rt deltoid 2nd, and MENACTRA left deltoid third. After injection of MENACTRA patient experienced syncopal episode with tonic clonic movements; patient transported to ER after 30 min of symptoms by squad.

Other Meds: None

Lab Data:

History: Allergy to penicillin

Prex Illness: None

Prex Vax Illns:

Vaers Id: **391150-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
1.5	M	27-Apr-2010	27-Apr-2010	0	22-Jun-2010	22-Jun-2010	TX	TX20100034PU	26-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MMR	MERCK & CO. INC.	1148Y		Right arm	Subcutaneously	
VARCEL	MERCK & CO. INC.	1444Y		Left arm	Subcutaneously	
DTAPIPVHIB	SANOFI PASTEUR	C3365AB		Left leg	Intramuscular	
HPV4	MERCK & CO. INC.	1257Y		Right leg	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB817BA		Left leg	Intramuscular	
PPV	UNKNOWN MANUFACTURER	E4530		Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash erythematous

Symptom Text: CLIENT WAS GIVEN 1 YEAR OLD SHOTS ABOUT 10:40AM. ABOUT 11AM, MOTHER CAME IN WITH CHILD. CHILD HAD A FINE RED RASH NOTED ON FACE AND BOTH ARMS. NONE NOTED ON BACK, STOMACH OR LEGS. CLIENT DID NOT APPEAR TO BE IN ANY RESPIRATORY DISTRESS. BENADRYL LIQUID WAS GIVEN AND TOLD TO WAIT FOR AWHILE IN WAITING AREA BEFORE LEAVING. AFTER ABOUT 20 MINUTES OR SO MOM STATED THAT SHE HAD TO LEAVE. CLIENT STILL DID NOT APPEAR TO BE IN ANY DISTRESS. RASH STILL NOTED ON FACE AND ARMS BUT NO OTHER PLACE. TOLD MOM TO GIVE BENADRYL AS DIRECTED AND IF CLIENT DEVELOPED ANY RESPIRATORY PROBLEMS OR RASH SPREAD TO TAKE TO ER AND TO TAKE SHOT RECORD WITH HER. GAVE MOM OUR PHONE# AND TOLD HER I WOULD CALL TO CHECK AND SEE HOW CLIENT WAS DOING NEXT DAY. BENADRYL WAS DISPENSED TO CLIENT 4/27/2010. 8:45AM 4/28/10 CALLED TO CHECK ON CLIENT BUT ANSWERING MACHINE CAME ON. I GUESS IT WAS THE FATHER. HE STATED HE WAS AT WORK AND TO CALL BACK AT 3:30 WHEN HE GOT HOME. 4:20PM 4/28/10 LEFT MESSAGE. WILL CALL AGAIN IN MORNING. 10AM 4/29 LEFT MESSAGE FOR 3RD TIME. 10:20 CLIENTS MOTHER CALLED AND SAID HE WAS DOING FINE. RASH IS RESOLVING BUT NOT COMPLETELY GONE. NO FEVER OR RESPIRATORY PROBLEMS. CON'T TO GIVE BENADRYL AS PRESCRIBED. DR. WAS NOTIFIED ON 4/28/10. RECOMMNEDATION: RASH WITHOUT ANAPHYLAXIS IN NOT CONTRAINDICTATION TO FURTHER IMMUNIZE. PREMEDICATION COULD BE CONSIDERED. The following information was obtained through follow-up and/or provided by the government. 8/26/10 Child did not receive any additional outside medical attention.\jc

Other Meds: NONE

Lab Data: NONE

History: NONE LISTED

Prex Illness: NONE LISTED

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391162-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	09-Jun-2010	09-Jun-2010	0	22-Jun-2010	23-Jun-2010	--	WAES1006USA01775	23-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Information has been received from a consumer concerning her daughter who on 09-JUN-2010 was vaccinated with a first dose of GARDASIL (lot number not provided). On 09-JUN-2010 the patient went unconscious and had a seizure. At the time of the report the patient's outcome was unknown. The patient sought unspecified medical attention. Upon internal review seizure was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 391163-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
40.0	M	Unknown	05-Mar-2008		22-Jun-2010	23-Jun-2010	FL	WAES0810USA01713	05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Adenocarcinoma, Biopsy, Carcinoembryonic antigen normal, Chemotherapy, Colectomy total, Colon cancer, Colonoscopy, Computerised tomogram abdomen, Computerised tomogram abnormal, Familial risk factor, Gastrointestinal oedema, Haemoglobin normal, Haemorrhoids, Intestinal mass, Intestinal ulcer, Laparoscopic surgery, Liver function test normal, Mean cell volume decreased, Neoplasm malignant, Off label use, Polyp

Symptom Text: Information has been received from a male in his forties who was vaccinated with 2 doses of GARDASIL (dose, therapy route unspecified). No AE reported. Follow up information has been received from the 43 year old male consumer indicated that he was vaccinated with two doses of GARDASIL before it was approved for men. He received the first dose of GARDASIL on 05-MAR-2008 and the second dose of GARDASIL on 23-APR-2008. He did not receive a third dose of GARDASIL. There were no lot number was provided. It was unknown if the patient sought medical attention. At the time of report the patient's status was unknown. Additional information has been received from the 43 year old male patient who was vaccinated with his first and second doses of GARDASIL in March 2008 and April 2008. The patient stated then he was diagnosed with colon cancer in October 2008. He underwent surgery and chemotherapy and he was in remission. No further information was available. Upon internal review, colon cancer was considered to be an other important medical event. Additional information has been received from a medical assistant concerning the 40 year old male patient (previously reported as 43 years old) was referred to a physician of gastroenterology and internal medicine. The patient was admitted to hospital on 30-OCT-2008. The patient had a laparoscopic anterior resection (hospitalization dates were not reported). It was reported that on 18-DEC-2008 the patient was admitted to hospital for a total abdominal colectomy (hospitalization dates were not reported). Additional information has been received from the medical assistant from the administering physician's office who stated that there was no documentation in the patient's chart that he received any GARDASIL vaccinations at the physician's office. Follow up information has been received from the physician via medical records indicated that the patient was a 41 year old male with a long history of irritable bowel, some rectal bleeding for about six months and a family history of colon

Other Meds: Unknown

Lab Data: laparoscopy, laparoscopic anterior resection; colectomy, 12/18?/08, a total abdominal colectomy; colonoscopy, 12/17?/08 see narrative; colonoscopy, 10/15/08, colon cancer

History: Colonoscopy; Biopsy; Adenoma benign; Rectal polypectomy; Colon cancer

Prex Illness: Irritable bowel; Rectal bleeding

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391164-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	26-Feb-2010	17-Mar-2010	19	22-Jun-2010	23-Jun-2010	--	WAES1006USA02402	23-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Quadriparesis

Symptom Text: Information has been received from a female consumer who on 22-DEC-2009 and 26-FEB-2010 was vaccinated with a first and second doses of GARDASIL (route and lot # not reported). On 17-MAR-2010 the patient experienced a seizure. The patient was now experiencing temporary paralysis in all four limbs. The patient's outcome was not reported. Upon internal review, seizure and temporary paralysis in all four limbs were determined to be other important medical events. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391167-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		22-Jun-2010	23-Jun-2010	--	WAES1006USA02403	23-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Tachycardia

Symptom Text: Information has been received from a physician concerning a 14 year old female who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route, and lot# not reported). On an unspecified date the patient experienced tachycardia while going through the GARDASIL series and was hospitalized. The patient's tachycardia persisted. Tachycardia was considered to be disabling by the reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391170-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	Unknown	Unknown		22-Jun-2010	23-Jun-2010	--	WAES1006USA02693	23-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a consumer concerning her son who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route, and lot# not reported). On an unspecified date the patient experienced a seizure 83 days after the shot was administered. Patient was now taking anti-seizure medication (name and manufacturer unspecified). The patient's outcome was not reported. Upon internal review, seizure was determined to be an other important medical event. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391175-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Jun-2010	14-Jun-2010	0	22-Jun-2010	22-Jun-2010	WI		22-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Convulsion, Dark circles under eyes, Fatigue, Gaze palsy, Immediate post-injection reaction, Loss of consciousness, Musculoskeletal stiffness, Pallor, Paraesthesia

Symptom Text: Received GARDASIL immunization - 1st dose, passed out immediately. Laid down and went into seizure-like symptoms, eyes rolling, very stiff body, hands clenched, lasted about 30 sec. She didn't remember anything. Very tired rest of evening and weak. She said her fingers tingled. Her eyes had very dark circles and she was very pale.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391182-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	09-Jun-2010	11-Jun-2010	2	22-Jun-2010	22-Jun-2010	IL		23-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0162Y	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0800Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: Site of injection reddened, hot to touch, raised, swollen, 3 inches in diameter.

Other Meds: BENTYL

Lab Data: None

History: Crohn's disease

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391212-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	22-Jun-2010	22-Jun-2010	0	22-Jun-2010	23-Jun-2010	MN		23-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaphylactic reaction

Symptom Text: Anaphylactic sx 30-45 min after HPV vaccine.

Other Meds:

Lab Data:

History: Hx headache, Obesity; Arm swelling after Tdap 4/29/2009

Prex Illness:

Prex Vax Illns:

Vaers Id: 391217-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	14-May-2010	Unknown		22-Jun-2010	23-Jun-2010	MA		23-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1333Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Impaired work ability, Radial nerve palsy

Symptom Text: Wrist drop syndrome radial nerve palsy on side of injection. Not able to work as she is a waitress.

Other Meds:

Lab Data: Mild (R) radial neuropathy with denervation distally to triceps; EEG-EMGB

History: Decreased K+ was treated at that time.

Prex Illness: Hypokalemia; Bulemia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391231-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Aug-2009	21-Jun-2010	306	23-Jun-2010	23-Jun-2010	MA		23-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3016AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1543X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0702X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Varicella

Symptom Text: Pt developed rash on 6/21/10. Seen in office 6/23/10 and dx with varicella. No associated symptoms.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **391277-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	03-Feb-2010	03-Feb-2010	0	23-Jun-2010	24-Jun-2010	PA	WAES1003USA01846	25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1480Y	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure before pregnancy, Pregnancy test urine

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a 23 year old female with no medical history who on 02-DEC-2009 was vaccinated intramuscularly with the first dose of GARDASIL (lot # 663454/0672Y, 0.5 ml). On 03-FEB-2010, the patient was vaccinated intramuscularly with the second dose of GARDASIL (lot # 661758/1480Y, 0.5 ml). There was no concomitant medication. The reporter became pregnant after receiving the vaccine. No adverse effect reported. Urine test was performed (result not provided). The LMP was 08-JAN-2010. The estimated delivery date was on 15-Oct-2010. At the time of the report, the outcome was unknown. Follow up information was received from the physician reported that the patient experienced an early miscarriage on an unspecified date. Upon internal review, an early miscarriage was considered to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 1/8/2010)

Prex Vax Illns:

Vaers Id: **391278-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		23-Jun-2010	24-Jun-2010	FR	WAES1006USA02831	25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Polyneuropathy

Symptom Text: Case received from a gynecologist on 16-JUN-2010. A female patient developed polyradiculoneuritis after she had received an injection of GARDASIL (batch number not reported) on an unspecified date. The reporter specified that the patient was the daughter of a patient of his. Unspecified investigations were performed in hospital. The physicians who took care of the patient did not incriminate GARDASIL. On the other hand, the patient's mother was convinced that there was a link with the vaccine. According to the reporter, the patient had "settled in handicap". He could not provide any further information regarding this case. At the time of reporting, the patient had not recovered. Polyradiculoneuritis was considered to be disabling. Other business partner numbers included E2010-03761. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **391319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jun-2010	22-Jun-2010	1	24-Jun-2010	24-Jun-2010	SC		25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1707Y	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3333AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0819Y	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Induration, Pain in extremity, Rash vesicular, Swelling

Symptom Text: Within 24 hrs of vaccination reported "knots with ? bumps. No fever. Returned Day 3, afebrile but with vesicular rash (Rt) mid deltoid. Painful, red, edematous. PN: HSVI-asymptomatic now.

Other Meds: ADDERALL 15mg; VENTOLIN Inhalation

Lab Data: viral culture sent 6/23/10

History: NKDA

Prex Illness: Asthma; ADD

Prex Vax Illns:

Vaers Id: **391337-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	M	10-Aug-2009	01-Mar-2010	203	24-Jun-2010	25-Jun-2010	--	WAES0908USA01718B1	25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Congenital anomaly, Conjunctivitis, Constipation, Cough, Crying, Drug exposure during pregnancy, Eye swelling, Eyelid margin crusting, Gastrooesophageal reflux disease, Hernia, Hydrocele, Infantile spitting up, Nasal congestion, Scrotal swelling, Upper respiratory tract infection

Symptom Text: Information has been received from a pediatrician via medical records concerning a male baby who was born to a 17 year old mother with mild intermittent asthma. On 10-AUG-2009 the mother was vaccinated with the first doses of GARDASIL (Lot # 662300/0100Y). On 09-MAR-2010, 37.6 weeks from LMP the mother delivered a normal, healthy male baby weighing 7 pounds, the mother delivered a normal, healthy male baby weighing 7 pounds, length 19.5 inches, apgar score 9.9, head circumference 13. The mother had no complication and no infections or illnesses during pregnancy. The mother had no complication during labor/delivery. On 19-MAR-2010, the baby was brought to the pediatrician's office. It was reported that the baby weighing 7.9 pounds, length 20 inches, head circumference 14, body temperature 99.1 degree F. The baby was fed every 2-3 hours and he had been spitting up. The baby was diagnosed with mild GERD. On 14-APR-2010, the baby had a one month follow-up visit. It was reported that baby weighing 9.13 pounds, length 21 5/8 inches, head circumference 14 3/4, body temperature 97.8 degree F. The baby ate well, still spitted but not much. It was reported that the baby's left eye had been crusted ever since birth, spitting up a lot. The mother put child back on SIMILAC advance because ENFAMIL AR was causing constipation. On 21-APR-2010, the baby was brought to th pediatrician's office. The baby had cough symptoms, and stuff nose with body temperature 99.2 degree F. It was reported that the baby ate well, weighing 9.5 pounds. The baby was diagnosed with upper respiratory infection (URI). On 03-MAY-2010, the baby was brought to the pediatrician's office. The baby was weighted 11.7 pounds, body temperature was 98.8 degree F. It was reported that the baby cried for 2 days non stop and he had balls swollen. The baby was diagnosed with hydrocele, GERD and ?small hernia. On 19-MAY-2010, the baby was brought to the pediatrician's office. The baby was weighted 12.8 pounds, body temperature was 98.4 degree F. It was reported that t

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 391338-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2009	12-Aug-2009	0	24-Jun-2010	25-Jun-2010	IN	WAES0911USA02039	25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Obstructed labour

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL, concerning a 17 year old female patient with allergy to codeine who on 23-AUG-2009 was vaccinated intramuscularly with the first 0.5ml GARDASIL (lot # not reported). Fatal ultra sound was performed. The patient was 22 weeks pregnant on 22-Oct-2009. The patient sought medical attention via office visit. Follow up information has been received from a registered nurse concerning a 17 year old female patient with no previous pregnancies who on 12-AUG-2009 (reported as 23-AUG-2009 previously) was vaccinated intramuscularly with a 0.5ml GARDASIL (lot # 662229/1497X). On 12-OCT-2009 ultrasound was performed and it was found the patient was 22+5 weeks pregnant and normal anatomy. The nurse reported the patient's last menstrual period was 04-MAY-2009 and the estimated delivery date was 07-FEB-2010. She also reported that the date of last menstrual period could also be 20-JUN-2009 and the estimated delivery date was 17-MAR-2010. Follow-up information has been received from a medical assistant (MA). The MA pulled the patient's chart and provided pregnancy outcome information. The patient had a cesarean section on 07-FEB-2010, secondary to having a "bony pelvis". She delivered a healthy, 7lb 14oz baby. The MA also added that there was "nothing in the report to indicate there were any problems with the baby." The patient had recovered and didn't have any post operation complications. Upon internal review, cesarean section secondary to having a "bony pelvis" was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Ultrasound, 10/12/09, gestation for 22+5 weeks, normal anatomy; ultrasound, pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 5/4/2009)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391339-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		24-Jun-2010	24-Jun-2010	FR	WAES1006USA03011	24-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death, Ovarian cancer

Symptom Text: Information has been received from a physician via CSL as part of a business agreement (manufacturer control # 20100617KC1) concerning a 16 year old female who on an unspecified date was vaccinated with a dose of GARDASIL (lot # not reported). After the GARDASIL vaccination, 3 months later, the patient died of ovarian cancer. The patient was treated at a women's hospital. The physician stated that there was no causal relationship between the vaccine and death. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391340-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Jun-2010	11-Jun-2010	0	24-Jun-2010	25-Jun-2010	NC	WAES1006USA03155	25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on approximately 11-JUN-2010 ("either the end of last week 07-JUN-2010 or in the beginning of this week 14-JUN-2010") was vaccinated with the first dose of GARDASIL (lot# not reported). On approximately 11-JUN-2010, immediately after receiving the first dose of GARDASIL, the patient began to seize, but the seizing resolved almost immediately as well. Unspecified medical attention was sought. The physician reported that the patient recovered the day she received the first dose of GARDASIL. Upon internal review, seize was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **391341-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Jun-2010	25-Jun-2010	FR	WAES1006USA03261	25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date, was vaccinated with GARDASIL (lot # not reported). Following the vaccination, the patient experienced dyspnoea. The patient needed to go to the emergency because of the dyspnoea. The outcome of dyspnoea was unknown. No further information was available at the moment. The reporting physician felt that dyspnoea was related to therapy with GARDASIL. The reporting physician considered that dyspnoea was an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391378-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Jun-2010	15-Jun-2010	0	24-Jun-2010	24-Jun-2010	NJ		24-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	U2936BA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3097AA	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site pruritus, Injection site swelling

Symptom Text: Bilateral injection sites red, burning, itching and swollen superficial scratches right arm. Immunization records were not provided at time of visit. Monitor sites.

Other Meds:

Lab Data:

History: Asthma

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391380-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	27-Aug-2008	03-Sep-2008	7	24-Jun-2010	24-Jun-2010	TX		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U3048AA	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal tenderness, Convulsion, Decreased appetite, Disorientation, Dizziness, Fall, Gastroenteritis, Gaze palsy, Grand mal convulsion, Headache, Hypoglycaemia, Loss of consciousness, Nausea, Respiratory rate increased, Syncope, Tetany, Tremor, Vomiting

Symptom Text: Never been ill her life - took vaccine and started having seizures. Have not stopped. The following information was obtained through follow-up and/or provided by the government. Hospital Discharge progress note/summary. Service date 9/1/08 to 9/2/08 Assessment: Syncope, suspected hypoglycemic episode. Patient arrived via EMS after syncope episode. Similar episode over the past week. Observed overnight and discharged. Neuro Consultant / PCP medical records / ER Note, received 6/29/10. Service dates 1/23/08 to 9/18/10 Assessment: Headache, Dizziness, Convulsions. On 9/3/10 arrives at ER. Bystanders say she was "Breathing fast and then lost consciousness." Flexing of hands and feet - carpal pedal spasm. 9/18/08 Neurology Consult - Tremulous/shaking while in tubing in lake. At school collapsed to ground, passed out, eyes rolled, curled up. Gets dizzy when getting up quickly or after hot bath. Frequent headaches. 12/9/09 - Brought to ER for seizure. Takes herbs for seizures no prescribed medications. Hospital / ED records received 7/1/10. Service dates 9/1/08 to 5/9/10. Assessment: Recurrent Grand Mal Seizure, Gastroenteritis, Mild Dehydration. Multiple ED visits and hospitalizations for seizures, disorientation. On 5/8/10 Patient presents because of recurrent seizure activity, nausea, vomiting, and decreased appetite. Trileptal. Abdominal tenderness.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. LABS and DIAGNOSTICS: Glucose 56 mg/dL (L). LABS and DIAGNOSTICS: Valproic Acid Level (L). CHEM - CO2 19 mEq/L (L) Total Protein 5.3 g/dl (L) Alb

History: none. The following information was obtained through follow-up and/or provided by the government. PMH: Chicken Pox. Sprain left middle and ring finger.

Prex Illness: None. The following information was obtained through follow-up and/or provided by the government. Patient presents on day of vac

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391402-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Jun-2010	23-Jun-2010	0	24-Jun-2010	25-Jun-2010	MN		25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1099Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3047AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Pt fainted immediately following h papilloma vaccine administration. Pt was placed in supine position with legs elevated. Pt regained consciousness in approx. 30 seconds, was monitored for 15 minutes, then released.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391410-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Jun-2010	24-Jun-2010	0	24-Jun-2010	25-Jun-2010	AZ		25-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061BA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3075AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Fatigue, Headache

Symptom Text: After receiving immunizations, patient became dizzy and light headed. BP 88/52 after a few minutes of laying down BP back to 121/71, but patient c/o headache and tiredness. Was able to walk out ok.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391411-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Mar-2008	15-Jun-2010	823	24-Jun-2010	25-Jun-2010	CA		05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pertussis

Symptom Text: Pt received Tdap (ADACEL) 3/14/08 and was diagnosed with pertussis 6/15/10.

Other Meds:

Lab Data: 6/15/10 Bordetella PCR

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391413-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Jun-2010	24-Jun-2010	1	24-Jun-2010	25-Jun-2010	WI		25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0318Z		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dysphagia, Headache

Symptom Text: 12-14 hours after getting injection woke up with headache, slight trouble swallowing, dizzy, temp 98.3. Mom gave BENADRYL.

Other Meds: LEXAPRO 10 mg; CLINDAMYCIN 1% Gel; TRETINOIN 0.05% cream

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391422-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Jun-2010	07-Jun-2010	0	24-Jun-2010	25-Jun-2010	OH		02-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1333Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic

Symptom Text: Patient developed an itchy rash that looked like goose bumps a few hours after getting HPV # 1. She was not ill and the rash was gone in 4-5 days.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **391423-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	24-Jun-2010	24-Jun-2010	0	24-Jun-2010	25-Jun-2010	AZ		25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1596Y		Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1378Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	0261Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Presyncope, Syncope

Symptom Text: GARDASIL given No 1 shot, then Hep A and VARIVAX. Patient completely fainted (at least 1 min). After wakening, turn pale and almost passed out again. After giving blow by O2 and laying flat at least 5 min, felt better. Sat up, stood up took 2 steps, went pale again and needed to lie down again. BP 90/60. Bl. sugar 117. After 3rd epis given epinephrine 0.3mg.

Other Meds:

Lab Data: Blood sugar 117; O2 stats 98-100; BP 90/60

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391438-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		25-Jun-2010	28-Jun-2010	FR	WAES1006ISR00020	28-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pulmonary embolism

Symptom Text: Information has been received from a gynecologist. The reporter indicated to have been receiving in the last 6 months, information concerning pulmonary embolism after the administration of GARDASIL. The reporter received the information from patients reading the internet or from other physicians who read or heard about the event. No other information is available. This is a hearsay report in the absence of an identifiable patient. Attempts are being made to verify the existence of a patient. Upon internal review, pulmonary embolism was considered to be an other important medical event. This report is one of several reports related by the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391439-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		25-Jun-2010	28-Jun-2010	--	WAES1006USA02143	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Condition aggravated, Convulsion, Death

Symptom Text: Information has been received from a Registered Nurse concerning an 18 year old female patient with a history of seizures prior to GARDASIL, who on an unspecified date was vaccinated with a dose of GARDASIL. The nurse advised that the patient experienced seizure and subsequent death after receiving GARDASIL. It was not advised which injection in the series caused the adverse experience or how the injection was administered. The health care professional was contacted by telephone and call would not supply the following information: patient name, date of birth, dates of vaccination/therapy, dose number, lot number and date of event. Seizure was considered to be disabling and immediately life-threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391461-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jun-2010	16-Jun-2010	0	25-Jun-2010	25-Jun-2010	MO	MO201013	25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3353AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1099Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Autonomic nervous system imbalance, Loss of consciousness, Similar reaction on previous exposure to drug, Unresponsive to stimuli

Symptom Text: Patient passed out and was unrespoinsive for 25-30 minutes in the evening after receiving immuniations per mother. Mother states had a similar episode in 2007 after receiving first Gardasil immunization. States had several evaluations in 2007 and diagnosed with autonomic nervous disorder. No episode after received second dose of Gardasil in 2008 at doctor's office.

Other Meds: Albuterol inhaler prn

Lab Data: x-rays, blood tests, urine tests

History: ASA allergy - C section on 5/20/10

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391462-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Jun-2010	25-Jun-2010	0	25-Jun-2010	25-Jun-2010	WI		25-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1070Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0671Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Syncope

Symptom Text: Patient stated she didn't feel well and requested a glass of water. RN assisted patient with her mother to lay down on a cot. Patient had a brief episode of syncope while RN was assisting to cot. RN gently lowered patient to floor with her mothers assistance and then the patient immediately gained consciousness.

Other Meds:

Lab Data:

History: No.

Prex Illness: No.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391477-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-Jun-2010	23-Jun-2010	2	25-Jun-2010	28-Jun-2010	IN		28-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3054AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: 6/23/10 developed hives on arms and legs. Treated with BENADRYL.

Other Meds:

Lab Data:

History: Allergic to CEDAX

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391487-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	21-Jun-2010	21-Jun-2010	0	25-Jun-2010	28-Jun-2010	MI		28-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1377Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: Telephone call on 6/22/10 at 1:00pm that right arm swollen from shoulder to fingertips that started 5:00pm on 6/21/10. Also right leg swollen from knee to her right foot, but able to wear her normal shoes. Denied numbness or tingling in right extremities. After discussion with Dr. an appointment was scheduled at a clinic for the client to be seen later on 6/22/10 with client in agreement. Telephone call on 6/23/10 and left message to call nurse back. Telephone call on 6/24/10 to patient and she states did not go to clinic appointment/cancelled it. Patient states all swelling gone by 10:00pm on 6/23/10 in both right arm and right lower leg.

Other Meds:

Lab Data: None

History: None

Prex Illness: No illness at time of vaccination

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391489-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	25-Jun-2010	25-Jun-2010	0	25-Jun-2010	28-Jun-2010	VA		28-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3383BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1377Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Mom states pt gets himself worked up for shots. Gave vaccines and pt ok pt got up to leave and got about 20 feet. Got lightheaded and dizzy was put in chair, didn't feel better after about 4-5 min so took to lay down, laid down after 10-15 min was ok when left.

Other Meds: None

Lab Data:

History: Migraine headache

Prex Illness: None

Prex Vax Illns:

Vaers Id: **391544-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	25-Jun-2010	26-Jun-2010	1	28-Jun-2010	28-Jun-2010	WI		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3069AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pain in extremity, Skin warm

Symptom Text: Arm painful red, swollen warm to touch. Seen in walkin care 6-26-10, ice-BENADRYL. Symptoms resolved.

Other Meds: MTV at times

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391559-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Sep-2009	30-Sep-2009	0	28-Jun-2010	29-Jun-2010	WA	WAES1001USA01015	29-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breech delivery, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse, for the pregnancy registry for GARDASIL concerning a 17 year old female with no known drug reactions or allergies and no pertinent medical history who on 30-SEP-2009 was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL (Lot # 662518/0087) while pregnant. LMP: 15-MAR-2009. EDD: 20-Dec-2009. Concomitant therapy included prenatal vitamins (unspecified). No adverse effect was reported. The patient sought unspecified medical attention. Follow up information was received from a registered nurse, concerning a 17 year old female patient, with history of colposcopy (on 11-AUG-2009), allergies and vaginal yeast infection. Concomitant therapy included vitamins (unspecified), MONISTAT and CLARITIN. The patient EED was also reported as 10-JAN-2010. On 21-MAY-2009, an ultrasound of routine was performed and showed: Viable pregnancy. On 18-DEC-2009, the patient delivered a healthy normal baby (ID 50705) and had a complication during labor/delivery specifically Breech-C section. Upon internal review breech C-section was considered an other important medical event. No further information was available.

Other Meds: Claritin; Monistat; vitamins (unspecified)

Lab Data: ultrasound, 05/21/09, Viable pregnancy

History: Vaginal yeast infection; Colposcopy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391561-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		28-Jun-2010	29-Jun-2010	--	WAES1006USA03478	29-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from an office registered nurse concerning a 16 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL. After receiving the vaccine the patient had a seizure. The patient sought unknown medical attention. The nurse reported that the patient was not receiving anymore doses of GARDASIL and was now on anti-convulsant medication (name and manufacturer unspecified) for the seizures. Additional information has been received from the registered nurse who indicated that the patient's mother had come to the clinic for a DEPO-PROVERA injection. The patient's mother stated that her daughter had received the first dose of GARDASIL at another physician's office (physician's name and contact information was not reported). The patient began to have seizures after she had received GARDASIL vaccination. The GARDASIL vaccinations were discontinued because it was not known if the GARDASIL vaccination had caused the seizures. The reporter stated that she did not know the patient's name or contact information and was not able to give any additional information. At the time of report the patient's status was unknown. Upon internal review, seizure was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391565-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Apr-2010	26-Apr-2010	11	28-Jun-2010	29-Jun-2010	FR	WAES1006USA02217	29-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ29410	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abnormal behaviour, Ataxia, Depressed level of consciousness, Paraesthesia, Photophobia

Symptom Text: Information has been received from the agency via a Case Line Listing via CSL, as part of a business agreement, concerning a 16 year old female who on 15-APR-2010 was vaccinated with first dose of GARDASIL (lot # NJ29410, batch # NK 30260), 0.5 mL, intramuscularly. On 26-APR-2010 the patient experienced ataxia (severe), photophobia (severe), paraesthesia (severe), behaviour abnormal (severe) and consciousness decreased (severe) and was hospitalized. At the time on the report the patient had not recovered. The relationship between GARDASIL and ataxia, photophobia, paraesthesia, behaviour abnormal and consciousness decreased was unclassified. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391573-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	M	17-Jun-2010	18-Jun-2010	1	28-Jun-2010	28-Jun-2010	OR		29-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3352AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB379AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Skin warm, Swelling

Symptom Text: 6/19 4" X 4 1/2 " area on right arm, hot, erythema, raised. Size increased next day but color tone duller. Ibuprofen 600 mg po tid with food X 7d. Ice local application. Discouraged use of right arm X 1 week.

Other Meds: Vitamin B6 50 mg qd; INH 300 mg po qd; Loratidine 10 mg po qd.

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391574-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	M	17-Jun-2010	18-Jun-2010	1	28-Jun-2010	28-Jun-2010	OR		29-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C3352AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB379AA	1	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1401X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: 6/19 Lt arm youth complained of pain, 3" diameter area of redness slightly raised and warm on Lt deltoid area. Recommended ice application, Ibuprofen 400mg PO PRN.

Other Meds: Trazodone 50mg

Lab Data: positive submandibular adenopathy NL, atraumatic

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391608-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Jun-2010	26-Jun-2010	0	28-Jun-2010	29-Jun-2010	IN		29-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3045AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1038Y	0	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3353AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1332Y	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0095Z	1	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U3212AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Loss of consciousness

Symptom Text: Pt recieved shots and left room. Went out to waiting room to wait for mother to check out, patient went down to her knees and then passed out and hit head on the floor.

Other Meds: None listed

Lab Data: Patient was brought into a room and laid down. Was given some food and water and had a cold cloth on her forhead. After 15min pt stated that she was fine and was released to go home. Instructed to call MD with any other problems or concerns

History: None Listed

Prex Illness: None Listed

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391636-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-Jun-2010	29-Jun-2010	0	29-Jun-2010	29-Jun-2010	ND		29-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1333Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Somnolence, Unresponsive to stimuli

Symptom Text: Pt first leaned forward and then leaned back in chair. Unresponsive. Moved pt to the floor and applied cold compress to forehead. Pulse was 60. Pt responded to verbal stimuli after lying on the floor. Was drowsy and oriented. After 5 minutes assisted pt to sit up on floor. Pt tolerated well. 8:35 am pt walked out of office without ill effect.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391637-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Jun-2010	28-Jun-2010	0	29-Jun-2010	29-Jun-2010	KS		29-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52BO49AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1013Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Skin warm

Symptom Text: Patient received a Tdap booster on 6-28-2010. Her last booster was 11-23-2009. Left arm was red and warm to touch after injection.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **391646-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Apr-2008	01-Apr-2008	0	29-Jun-2010	30-Jun-2010	--	WAES1006USA03314	06-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Acne cystic, Activities of daily living impaired, Alopecia, Arthralgia, Asthenia, Blood test normal, Computerised tomogram normal, Convulsion, Crying, Depression, Disturbance in attention, Dizziness, Fatigue, Gaze palsy, General physical health deterioration, Joint stiffness, Menstrual disorder, Migraine, Muscle twitching, Myalgia, Nausea, Pain, Pallor, Psychiatric symptom, Scan brain, Syncope

Symptom Text: Information has been received from parents concerning their daughter who in April 2008, was vaccinated with the first dose of GARDASIL (LOT# not reported). The parents reported that their daughter was a healthy, energetic, outgoing, active beautiful girl until the April 2008 when she was administered her first GARDASIL shot. From that day forward, her quality of life has drastically deteriorated. It started when the plunger of the syringe hit the bottom of the tube and she turned pale white, her eyes rolled back in her head; she twitched (as if she was having a seizure) and fainted. For the past two years, their daughter has been suffering debilitating stomach pain, severe migraine headaches, severe hair loss, severe dizziness, severe muscle & joint pain, severe fatigue & weakness, severe seizures & fainting, severe cystic acne and severe menstrual abnormalities, every single one of these painful changes in her life are severe, not mild or normal. The parents stated that they have made numerous trips to doctor's offices, specialists, alternative medicine practitioners, dermatologists and ER room. She has made numerous CT scans of the stomach and brain as well as many blood tests and general evaluations. All of these tests hadn't been able to determine the cause of her problems but they started when she was given the GARDASIL shot. Their daughter's life had greatly deteriorated over the past 2 years and continued to do so. On her good days she felt sick to her stomach, tired and didn't want to do anything but lay around. She was starting to demonstrate signs of depression; she didn't want to go visit with her friends anymore because of the constant pain. She was falling behind in her school work because she couldn't concentrate. Her acne was so bad and she was ashamed to go outside of the house. The parents stated that their daughter (who was an actress) had lost much of her confidence, due to the acne and constant pain, and wasn't able to audition with the same sparkle she once had. She was a very active girl who

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **391655-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	23-Jun-2010	23-Jun-2010	0	29-Jun-2010	30-Jun-2010	WA		30-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365AA		Left leg	Intramuscular	
	MNQ	SANOFI PASTEUR	U3048AA		Left leg	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y		Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Vomiting

Symptom Text: 10:15 - PT was given 3 vaccines: HPV in (R) thigh, and MCV and hepatitis A in (L) thigh. She was in supine position. Afterwards Pt stood up and became dizzy and pale. Sat down with water, voiced concerns of vomiting, and then said she felt better. 10:25 - MD was brought into room, talked to PT. MD said common s/e of HPV are dizziness, paleness. Pt soon then bent over and vomited twice. Pt was helped onto exam table. 10:30 - PT was given a cold cloth for her forehead, and immediately voiced, "I feel better." Vitals were monitored. Pt remained in office x 10 minutes for observation. She was slowly brought into standing position again. MD asked father to keep PT's activities "light for the day." Father agreed, and Pt left clinic with father.

Other Meds: no other meds

Lab Data:

History: healthy child, no allergies or previous problems

Prex Illness: well child visit

Prex Vax Illns:

Vaers Id: 391657-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jun-2010	19-Jun-2010	2	29-Jun-2010	30-Jun-2010	CA		30-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	03182		Right arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBV13799AA		Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	V3362AA		Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1747Y		Left arm	Subcutaneously	
TDAP	SANOFI PASTEUR	C3475AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Erythema, Musculoskeletal stiffness, Oedema peripheral

Symptom Text: Red swollen arm, neck stiffness, confusion lasted 3 days +

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **391661-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	23-Jun-2010	23-Jun-2010	0	29-Jun-2010	30-Jun-2010	CA		02-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1228Y	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3061AA	0	Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB362BA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Vision blurred

Symptom Text: Pt light headed states vision blurry. Sat down for a bit then layed down. Parents with pt. Pt felt better and went home. Some sweating.

Other Meds: PPD

Lab Data: None, Heart rate regular & breathing.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391702-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Mar-2010	09-Mar-2010	0	29-Jun-2010	30-Jun-2010	GA		01-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB327AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1317Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Syncope

Symptom Text: HPV #1 & Hep A administered on 3/9/10. Pt waited 30 minutes in clinic with no problems. Pt. came in 5/10/10 and informed me that on 3/9/10 she became anxious and fainted. Her mother called 9-1-1 and she was taken to the ER. ER visit WNL and patient was put on XANAX PRN by MD. Pt stated she became anxious that night when she started thinking about and reading the possible side effects of the HPV vaccine.

Other Meds: METRONIDAZOLE

Lab Data: Per pt., CAT scan and heart monitor all WNL. Pt. diagnosed with anxiety + 1yr ago. Pt in ER around 1 or 2 AM (client unsure).

History: Anxiety (diagnosed + 1 yr ago).

Prex Illness: Bacterial vaginosis

Prex Vax Illns:

Vaers Id: **391737-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	22-Jun-2010	23-Jun-2010	1	29-Jun-2010	30-Jun-2010	AZ		30-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1592Y	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	1446U	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3021AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3098BA	0	Left arm	Intramuscular	
IPV	SANOFI PASTEUR	D00372	4	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Crying, Headache, Pain in extremity, Pyrexia, Vaccination complication

Symptom Text: Mother called in am of day following vaccinations (6/23) to report that child had "slight fever, headache, sore arm." RN advised her to give him ibuprofen and monitor if condition worsened. Mother called back later in day to report that he no longer had a fever or sore arm, but that he "had a severe headache" and was "not able to get up and was continually crying." Mother was then advised to take him to Urgent Care/ER. Telephone follow-up was done with mother the next day (6/24), and she reported that she did take him to ER, and they checked him out. Says she was told it was "probably a vaccine reaction since he got several shots." Says that he had no more problems, and had completely recovered.

Other Meds:

Lab Data: Mother reported blood work done at hospital.

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391744-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jun-2010	29-Jun-2010	0	29-Jun-2010	30-Jun-2010	CA		30-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049BA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	0819Y	1	Unknown	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB388AA	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope episode lasting 10 sec.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: ~HPV (no brand name)~UN~12.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391759-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Jun-2010	07-Jun-2010	0	29-Jun-2010	30-Jun-2010	OH		30-Jun-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037AA	5	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1238Y	1	Left arm	Subcutaneously	
MEN	SANOFI PASTEUR	U3018AA	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Infection, Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Pain, swelling, and redness of tricep area of left arm since vaccine given on 6/7/10 pt treated for infection 6/9/10 infection improved 6/11/10 following first Gardasil vaccination. Mother certain the vaccine was Gardasil. The staff who administered the vaccines noted that varicella was given in the tricep area and the Gardisil was administered in the deltoid of left arm.

Other Meds:

Lab Data: pt received varicella 12/04/1998 without incident.

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391780-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		30-Jun-2010	01-Jul-2010	--	WAES1006USA03781	05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervix carcinoma

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route and lot# not reported). On an unspecified date the patient was diagnosed with cervical cancer. The patient sought unspecified medical attention. At the time of the report, the patient's outcome was unknown. Upon internal review, cervical cancer was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 391781-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	02-Jun-2010	02-Jun-2010	0	30-Jun-2010	01-Jul-2010	FR	WAES1006USA04015	01-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Erythema, Hypersensitivity, Lip swelling, Oedema mouth, Oropharyngeal pain, Pain, Pain in extremity, Pruritus, Pyrexia, Rash generalised, Respiratory tract infection, Tenderness, Urticaria

Symptom Text: Information has been received from a Health Authority (NO-NOMAADRVE-FHI-2010-10675, FHI 10-1346) concerning 12 year old girl who was vaccinated with GARDASIL (dose 3, batch number not reported, 1 d.f. parenteral) on 02-JUN-2010. HA coded fever, urticaria generalized (verbatim: itching and rash whole body) with onset on 02-JUN-2010. HA coded events with onset on 03-JUN-2010: erythema (erythema papulous and circular, distributed around joints of knee, elbow, wrist, finger foot and toe, arthralgia (pain in legs when walking, started in wrists), swelling lips (swelling around the mouth), and throat sore. Causality possible for all events. The patient had medical history of otitis and was treated with APOCILLIN (mfr unknown, start date is unknown). Treatment with APOCILLIN, due to otitis media, was completed on 01-JUN-2010. It was reported that the girl developed urticaria covering the whole body six hours post vaccination. She also experienced fever the same day. On 03-JUN-2010 she developed additional symptoms of pain in wrists and legs when walking, papulous and circular erythema distributed around joints of knee, elbow, wrist, finger, foot and toe and tenderness. She also swelled around her mouth and she experienced a sore throat. Tests performed on 03-JUN-2010 showed body temperature 38.2 C and pulse rate 128, regular (no unit reported). Tests performed on 04-JUN-2010 showed: white blood cell counts 15.4-12.8 (no unit reported), differential white blood cell count: neutrophiles 85-84%, lymphocytes 9-10%, C-reactive protein 12-18 (no unit reported) and red blood cell count sedimentation rate 13 (reframes not reported). Since onset of urticaria and general symptoms were few hours after vaccination, a strong allergic reaction to the vaccination were suspected. Other explanation was considered as reaction to concomitant respiratory tract infection, otitis and the antibiotic treatment. The outcome for fever was recovered (on 04-JUN-2010). The outcome of erythema, tenderness, arthralgia, swelling lips, urticaria genera

Other Meds: APOCILLIN

Lab Data: PVC/total heartbeat ratio, 03Jun10, pulse rate 128; body temp, 03Jun10, 38.2 C; WBC count, 04Jun10, 15.4-12.8; lymphocyte count, 04Jun10, 9-10 %; neutrophil count, 04Jun10, 85-84 %; serum C-reactive protein, 04Jun10, 12-18; erythrocyte sedi

History: Otitis

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391782-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		30-Jun-2010	01-Jul-2010	FR	WAES1006USA03865	05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hodgkins disease

Symptom Text: Information has been received from a physician concerning a 14 year old female who on an unspecified date was vaccinated with 3 doses of GARDASIL (batch numbers not reported). In late MAY 2010, the patient was diagnosed Hodgkin's syndrome. The outcome was not reported. Upon internal review, Hodgkin's syndrome was considered to be an other important medical event. Other business numbers include: E2010-03687. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 391788-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Jun-2010	29-Jun-2010	12	30-Jun-2010	30-Jun-2010	VA		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0318Z	2	Left arm	Intramuscular	FLUN HPV4

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Blood glucose increased, Diabetic ketoacidosis, Intensive care, Malaise, Muscle spasms, Polydipsia, Polyuria, Type 1 diabetes mellitus, Vomiting

Symptom Text: Diagnosis JODM made with patient presenting in DKA. The following information was obtained through follow-up and/or provided by the government. 7/6, 7/7, 7/8, & 7/13/10 Outpatient, ED, Hospital records and discharge summary received for dates of service 9/15/09 to 7/1/10. Dx: New onset IDDM, Diabetic ketoacidosis. Presented to ED with 1 wk. hx. of polyuria and polydipsia. Started to have leg cramps the day prior to admission and was not feeling well. Started vomiting morning of admission and continued to vomit every half hour. Had multiple episodes of vomiting. In ED noted to have a high blood sugar. IV of normal saline infused in ED and IV Zofran given. Insulin Infusion started and pt. admitted to PICU for monitoring. Hospitalized from 6/29/10 to 7/1/10. Endocrinology consulted. Diabetic education initiated. Discharged to home with diet and insulin plan.

Other Meds:

Lab Data: BS 450 CO2 11 Bun 22 Cr 0.8 The following information was obtained through follow-up and/or provided by the government. 7/6, 7/7, 7/8, & 7/13/10 Outpatient, ED, Hospital records and discharge summary received for dates of service 9/15/09 to

History: none

Prex Illness: none documented

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391789-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Jun-2010	30-Jun-2010	0	30-Jun-2010	30-Jun-2010	FL		30-Jun-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1316Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Loss of consciousness, Syncope

Symptom Text: PATIENT FAINTED AND COMPLAINED OF SLIGHT HEADACHE AFTER SHE CAME TO. PATIENT WAS ONLY PASSED OUT FOR APPROXIMATELY 30 SECONDS OR LESS.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **391810-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	M	30-Jun-2010	30-Jun-2010	0	30-Jun-2010	30-Jun-2010	MO		06-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	BAC52B05288	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	BAHAVB365AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	CU3333AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	D0969Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness

Symptom Text: Patient received TDAP, Hepatitis A, MENACTRA, and GARDASIL vaccines (in that order). Three seconds after administration of GARDASIL, patient lost consciousness for approximately 10 seconds. She had no difficulty breathing after the incident. I recognize there is a higher rate of vasovagal reactions with GARDASIL. Patient received no injuries due to her reaction.

Other Meds:

Lab Data:

History: Seasonal Allergies; Asthma

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391812-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jan-2008	21-Jun-2010	900	30-Jun-2010	30-Jun-2010	FL		06-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2402AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1522U	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1259U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysplasia, Papilloma viral infection

Symptom Text: Abnormal Pap smear with mild dysplasia and HPV present on smear.

Other Meds:

Lab Data: Positive HPV on pap smear

History: Asthma, allergies

Prex Illness: None

Prex Vax Illns:

Vaers Id: 391817-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Feb-2007	26-Mar-2007	49	30-Jun-2010	01-Jul-2010	OK		09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U1875AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1208F	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Dehydration, Fatigue, Feeling cold, Hypothyroidism, Intensive care, Irritability, Lethargy, Metabolic acidosis, Thirst, Type 1 diabetes mellitus, Weight decreased

Symptom Text: Over a 3 week period patient lost 20 pounds, extremely tired, & dehydrated. On 3-26-07 she was diagnosed with Type 1 Diabetes and Hypothyroid. She was admitted with a 1075 blood sugar. No family history of Diabetes. The following information was obtained through follow-up and/or provided by the government. 7/1/10 Received medical records for DOS 2009. Awaiting medical records from 2007. 7/9/10 Received PCP office records for 2/5/2007. FINAL DX: right otitis media w/perforation records reveal patient with right ear pain x 3 days with drainage x 2 days & hearing loss. Right anterior cervical lymph node tender & enlarged. Tx w/oral antibiotic & ear gtts. RTC 2/21/07 for ear check. Feeling better & balance had improved. Dx resolved right OM. 7/20/10 Received PCP office records & ER records for 3/26/07. FINAL DX: new onset IDDM; metabolic acidosis; dehydration; hypothyroidism 3/26/07 vs reveals patient experienced wt loss over 4 wks, lethargic, irritability, unable to get enough to drink, feeling cold. Oral mucosa very dry. Tx w/IVF & insulin, then admitted to ICU. No d/c summary available.

Other Meds:

Lab Data: Doctor ran all tests and blood work. The following information was obtained through follow-up and/or provided by the government. 7/20/10 Received medical records w/LABS: sodium 134(L), glucose 1079(H). HgbA1C 14.4(H). Urine glucose .1000(

History: seasonal allergies

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391828-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Jun-2010	22-Jun-2010	1	30-Jun-2010	01-Jul-2010	NC		02-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3056AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1605Y	0	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1318Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site warmth

Symptom Text: Sore, red, warm area at the site of the HPV. Recommended cool compresses, MOTRIN and started KEFLEX.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391835-1** **Related reports:** 391835-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jun-2010	29-Jun-2010	0	01-Jul-2010	01-Jul-2010	VA		01-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Passed out, lost consciousness for 10-20 seconds.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **391835-2** **Related reports:** 391835-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jun-2010	29-Jun-2010	0	13-Jul-2010	14-Jul-2010	VA		14-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	A0651X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Fall, Loss of consciousness

Symptom Text: We were discussing family planning issues and her upcoming trip when I gave the nurse authorization to administer the Gardasil which she did in the left deltoid area. The patient did not report any immediate discomfort at the injection site. Approximately 3 minutes later, while still sitting chatting comfortably on the exam table, she suddenly reared back and pitched sideways off the table, impacting with her head on the floor, apparently unconscious. I opened the airway and stabilized the cervical spine and called for help as well as having the staff alert her mother who was, at that time, in the waiting room. I advised transport to an emergency room for cervical spine films. No seizure activity was seen. I estimate that she was unconscious for approximately 10 seconds. She was briefly confused but regained orientation quickly. She indicated that one of her lower incisors appear to be chipped; indeed, a small fragment of the tooth margin was recovered (less than 2 mm). The cervical spine was maintained in a stable position until 911 arrived and applied a rigid cervical collar and moved her to a backboard. She was able to move all 4 extremities without difficulty. Her mother indicated that she would like to have her proceed with the rest of the immunization series, but lying down next time..

Other Meds: n/a

Lab Data: n/a

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **391895-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Jul-2010	01-Jul-2010	0	01-Jul-2010	02-Jul-2010	NC		02-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3055AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1539Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B037AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Foaming at mouth, Muscle spasms, Opisthotonus

Symptom Text: pt rec'd Boostrix and Gardisil in LD and then Hep A and Menactra in RD. As nurse was injecting the menactra, she felt the muscle spasm. Nurse completed injection and looked up at patient who was "foaming at the mouth" and back was arched and arms were jerking. Assisted patient to floor but aroused within a few seconds. VSS immediately after event.

Other Meds: NONE

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391915-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Jun-2010	29-Jun-2010	1	01-Jul-2010	02-Jul-2010	MT		06-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3060AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Injection site pain, Vomiting

Symptom Text: In the night 12 hours after injections high temp 101 degrees. Vomited next morning x 1. No local reaction other than soreness at injection site (L)>(R) mother reported at 10 am. Instructed to treat fever, clear liquids advance as tolerated. Mom calls again at 1:15 pm 6-29-10 to report fever now 100.2 degrees but has headache (moderate) "doesn't feel well at all". Instructed to use TYLENOL or ADVIL for fever + headache-which they did not treat earlier as instructed. 5:00 pm (TC) no fever after 2 TYLENOL no headache up and around-just tired. 6-30-10 (TC) all symptoms gone. Normal state of health.

Other Meds: Multi Vitamin

Lab Data: None

History: Amoxicillin allergy->rash; otherwise none

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391936-1** **Related reports:** 391936-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Jun-2008	20-Jun-2008	0	02-Jul-2010	06-Jul-2010	--	WAES0807USA02217	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a registered nurse for the pregnancy registry for GARDASIL concerning a 18 year old female who on 20-JUN-2008, was vaccinated with the first dose of GARDASIL (Lot# 658558/1061U). The patient was pregnant when the vaccination was given (LMP was not reported). No symptoms were noted. The patient sought unspecified medical attention. Follow up information has been received from the program assistant, who reported that the baby girl was born prematurely on 12-JAN-2009 at 32 weeks of gestation. Birth weight was 4 lbs 3 oz. There was no mention of any birth defects. Preterm labor at 32 weeks was considered to be an other important medical event. The infant's experience has been captured in WAES 0807USA02217B1. No further information is available.

Other Meds: Unknown

Lab Data:

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **391936-2 (S)** **Related reports:** 391936-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.6	F	Unknown	12-Jan-2009		02-Jul-2010	06-Jul-2010	--	WAES0807USA02217B1	02-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Premature labour

Symptom Text: Information has been received from a Program Assistant concerning a 7 month old female baby whose 18 year old mother was vaccinated IM on 20-JUN-2008 with 0.5 ml first dose of GARDASIL (Lot# 658558/1061U). Her LMP was not reported. Concomitant therapy included caffeine, citrated. The Program Assistant reported that on 12-JAN-2009, the baby girl was born prematurely at 32 weeks gestation. Birth weight was 4 lbs 3 ounces. The infant was on premature formula for some time and experienced colic, lactose sensitivity and spitting up (date unspecified). The baby was on caffeine, citrated at 1 month but no mention of when it was started. No birth defects mentioned. There was a non specific diagnosis at 9 months. The baby was being seen by neurologist for head control and eyes crossing in August 2009. The Program Assistant reported that she was not sure exactly when the shaken baby syndrome was discovered, however it was before August 2009 and she thought before 7 months of age. The first note about shaken baby syndrome was at the baby's 1 year check up. The baby had been hospitalized for 2 days (dates not provided) for brain damage related to the shaken baby syndrome. She also mentioned that the mother and baby come to the health department "or other services". Upon internal review, Baby was born prematurely at 32 weeks, on 12-JAN-2009 was determined to be an other important medical event. The mother's experience has been captured in WAES 0807USA02217. Additional information ahs been requested.

Other Meds: caffeine, citrated

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391937-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Jun-2010	20-Jun-2010	3	02-Jul-2010	06-Jul-2010	FR	WAES1006USA03991	07-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ53440	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Information has been received from a physician concerning a 14 year old female with no concurrent condition or medical history who on 17-JUN-2010 was vaccinated with the first dose of GARDASIL (lot# NJ53440, batch # NK45930) into the left arm. Three days after vaccination (on 20-JUN-2010) the patient experienced oedema of left arm and erythema of left arm. The patient's mother was nurse, so she gave her daughter one tablet of DITHIADEN and symptoms disappeared till the next day (21-JUN-2010). The reporting physician stated that this event was medically significant. The reporter felt that oedema of left arm and erythema of left arm were related to therapy with GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391938-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	01-Feb-2010		02-Jul-2010	06-Jul-2010	FR	WAES1006USA04244	07-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a physician concerning a 21 year old female patient that received the 3 doses of GARDASIL (lot number not reported) in 2008, according to the correct vaccination schedule (Months 0, 2, 6). She subsequently developed multiple sclerosis, confirmed in February 2010. No further information was provided. At the time of reporting, she had not recovered. Multiple sclerosis was determined to be an other important medical event. Other business partner numbers include E2010-03830. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **391966-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Jun-2010	28-Jun-2010	0	02-Jul-2010	07-Jul-2010	IN		07-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor

Symptom Text: Approx. 3 mins after giving GARDASIL immun. Pt became very pale in color. Mom states "looked like she was having a seizure". Pt was placed on floor, legs elevated. Dr was called to room to check patient. BP was taken; pt was moved & observed x 1/2 hour in another room. Cold compress applied to forehead, H2O given to drink.

Other Meds:

Lab Data: BP; none

History:

Prex Illness: Anemia; on menses

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391971-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	01-Jul-2010	01-Jul-2010	0	02-Jul-2010	02-Jul-2010	ND		02-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1333Y	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1330Y	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Rash on both arms & stomach.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391972-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-Jun-2010	24-Jun-2010	1	02-Jul-2010	02-Jul-2010	WI		02-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	SANOFI PASTEUR	U3082BA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1377Y	0	Left arm	Intramuscular	
	PPV	MERCK & CO. INC.	1047Y	0	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthma, Condition aggravated

Symptom Text: Asthma attack.

Other Meds:

Lab Data:

History: allergies, asthma

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391979-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jul-2010	Unknown		02-Jul-2010	07-Jul-2010	CA		07-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB431AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1497X		Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1294Y		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3075AA		Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B039AA		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope, Tremor

Symptom Text: Immediate syncope after application of GARDASIL with less than 3 sec. tension of body. Immediate spontaneous recovery.

Other Meds:

Lab Data: None.

History: Asthma; Depressive Do.

Prex Illness: Asthma stable; Depressive do

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **391989-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	30-Jun-2010	01-Jul-2010	1	02-Jul-2010	07-Jul-2010	CA		07-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1778Y	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3357AA	5	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	V3098AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain, Swelling

Symptom Text: Advice to apply cool compress, and gave BENADRYL and return if swelling, erythema or pain increase.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392015-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	02-Jul-2010	03-Jul-2010	1	03-Jul-2010	06-Jul-2010	NH		06-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1332Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Face oedema, Headache, Oral pruritus, Pruritus, Rash papular, Stomatitis

Symptom Text: She noticed itchiness and a soft bump inside her mouth at 1am. On July 3 in the morning she noticed that the right side of her face is edematous, she has a papular rash on her lower abdomen, and her arms and legs are itchy (no rash now, but she had 20 bumps right on right lower leg last night which have resolved). She also had a headache 7/2 in the evening.

Other Meds:

Lab Data: None done, observing. Recovery unknown as this has just happened.

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392026-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-Jun-2010	21-Jun-2010	0	05-Jul-2010	06-Jul-2010	MI		06-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	UNKNOWN MANUFACTURER	NULL	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Fatigue, Immediate post-injection reaction, Malaise, Musculoskeletal stiffness, Pallor, Syncope, Unresponsive to stimuli

Symptom Text: About two minutes after vaccinated patient turned white, said a word, fainted with stiffness (or seized?), eyes open, clenched fists, groaned aloud, was caught while tipping over, nonresponsive to verbal calls, episode lasted abut 70 seconds. Patient had no recollection of episode. Patient exhauseted and felt unwell for more than 5 hours afterward. Nurse was prsent and asked parent if patient had ever had a seizure, doctor was summoned. Doctor arrived as episode ended. Doctor and nuse informed patient she fainted. They took her blood pressure and had her lay down for 5 minutes then was sent home.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392031-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	14-Jun-2010	21-Jun-2010	7	05-Jul-2010	06-Jul-2010	MI		06-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	13774	2	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3049BA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Muscular weakness, Oedema peripheral

Symptom Text: Large amount of swelling left arm lasted for 1 week, swollen up to her neck. Some weakness of left arm. Persistent generalized fatigue at time of exam.

Other Meds:

Lab Data:

History: ADHD; UTI one month prior

Prex Illness: Healthy

Prex Vax Illns:

Vaers Id: **392069-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	16-Oct-2006	01-Dec-2009	1142	06-Jul-2010	08-Jul-2010	GA		12-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52802AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2539AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1448U	2	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1472U	1	Right leg	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Raynauds phenomenon, Skin discolouration

Symptom Text: Feet & toes turn white when outside, Raynaud's phenomenon.

Other Meds:

Lab Data: low ANA

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392070-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		06-Jul-2010	07-Jul-2010	--	WAES1006USA03948	07-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hodgkins disease

Symptom Text: Information has been received from a registered nurse who heard from another person that during a support group meeting for parents with kids with Hodgkin's disease, a couple of mothers mentioned that their daughter received GARDASIL before being diagnosed with Hodgkin's disease. The patients sought unspecified medical attention. At the time of the report, the patients' outcome was unknown. The nurse was not sure how many patients were involved it was all hearsay. This is a hearsay report in the absence of an identifiable patient. Attempts to verify the existence of a patient have been unsuccessful. Upon internal review, "Hodgkin's disease" was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **392071-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Jun-2010	09-Jun-2010	0	06-Jul-2010	07-Jul-2010	FR	WAES1006USA04451	07-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Back pain, Balance disorder, Dizziness, Feeling cold, Flank pain, General physical health deterioration, Headache, Hyperhidrosis, Kidney small, Nausea, Night sweats, Pyrexia, Tenderness, Vomiting

Symptom Text: Information has been received from a Health Authority (reference # NO-NOMAADVRE-FHI-2010-10710) concerning a 13 year old girl who on 09-JUN-2010 was vaccinated with a third 0.5 ml dose of GARDASIL (batch number not reported, parenteral route of administration). Health Authority coded pain back, vomiting (vomiting twice), nausea, dizziness, flank pain, sweating (exceeded sweating at night), headache, abdominal pain (pain right flank), unsteadiness, feeling cold, reduce general condition, tenderness (arm tenderness) and fever. Onset for all events was 09-JUN-2010, hours after vaccination. Causality is possible for all events. The patient was hospitalized from 09-JUN-2010 to 11-JUN-2010. The patient was treated with PARACET (Manufacturer Unknown) and IBUX (Manufacturer Unknown). On 09-JUN-2010, the body temperature was 39.5 degrees C. On 10-JUN-2010, number of examinations were carried out: aspartate aminotransferase: 84 (no unit reported), alanine aminotransferase: 60 (no unit reported), urinalysis: urine stix negative, gamma-glutamyl transferase: 16 (no unit reported), kidney ultrasound: left kidney small for her age, 8 cm in diameter, body temperature: 38.1 degrees C up to 39 degrees C and C-reactive protein: 8-77. There was no suspicion of underlying causes to the observed symptoms. The patient still had pain right flank when discarded from the hospital, but no tenderness over the kidney lodgers. The outcome was recovered for all events, except for pain right flank. The case is close. Other business partner numbers include E2010-03958. No further information is available.

Other Meds: Unknown

Lab Data: Renal ultrasound, 10Jun10, left kidney small for her age, 8 cm in diameter; Body temp, 09Jun10, 39.5 degrees C; Body temp, 10Jun10, 38.1 up to 39 degrees C; Serum C-reactive protein, 10Jun10, 8-77; Serum alanine aminotransferase, 10Jun10, 6

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392123-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Jul-2010	06-Jul-2010	0	06-Jul-2010	08-Jul-2010	ME		27-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	NULL	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Presyncope, Vomiting

Symptom Text: Near syncope and multiple seizure with multiple episodes of vomiting. 911 alerted - pt released to mother, transport refused - released to parent.

Other Meds: PPD; Sanofi; C3507AA; LT Arm; ID; 0

Lab Data:

History: Seizure; Allergy to VERSED

Prex Illness: None known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392131-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Feb-2007	29-Jan-2008	341	06-Jul-2010	08-Jul-2010	GA		09-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0187U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia areata, Thyroiditis

Symptom Text: Thyroiditis 01/29/2008 resolved, alopecia areata 5/2008 resolved.

Other Meds: On 01/29/2008 patient received HPV #2 & MCV4 @ which time an enlarged thyroid was noticed. At a later date (5-08) patient developed alopecia areata. Sibling had ? autoimmune response to HPV case #E-44612.

Lab Data: Thyroid Peroxidase 24 H (0-20)

History: At 15 2/12 check up mild thyromegaly noticed T4/TSH ordered.

Prex Illness: No

Prex Vax Illns:

Vaers Id: **392133-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	M	24-Jun-2010	24-Jun-2010	0	06-Jul-2010	08-Jul-2010	TX	TX20100070PU	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1328Y		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3061AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: 6/24/10 1113AM PATIENT HAD A SYNCOPAL EPISODE 2-3 MINUTES AFTER IMMUNIZATIONS ADMINISTERED.

Other Meds: NONE

Lab Data: B/P 140/50 PR 60 R 16 AFTER 5 MINUTES BP 118/72

History: ALLERGIC TO CECLOR

Prex Illness:

Prex Vax Illns:

Vaers Id: **392135-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Jul-2010	01-Jul-2010	0	06-Jul-2010	08-Jul-2010	PA		09-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB379AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1013Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Flatulence, Headache, Hypotension, Nausea, Pyrexia, Vomiting

Symptom Text: Became dizzy, light-headed, no loss of consciousness but BP slightly low. Had client lie down. Complained of gas pains. Client felt fine after half hour. Next day mother called to say child running 102-103 fever, severe headache, nausea. Vomited once on 7/1 and twice on 7/2. Advised to call family doctor/emergency room and to call back. No return call to see how child doing. Called again 7/6 with no return call from parent.

Other Meds:

Lab Data:

History: none stated

Prex Illness: none stated

Prex Vax Illns:

Vaers Id: 392255-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
47.0	F	08-Jun-2010	08-Jun-2010	0	07-Jul-2010	08-Jul-2010	VA	WAES1006USA04290	09-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0821Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Discomfort, Hypoaesthesia, No reaction on previous exposure to drug, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 47 year old "transplant" female patient with allergy to gentamicin, alpha-1 anti-trypsin deficiency and a history of influenza vaccination in September 2009 who on 15-MAR-2010 was vaccinated IM with her first 0.5 ml dose of GARDASIL (lot #663559/1178Y), which was required in order to be put on the transplant list. Concomitant therapy included vitamin D (unspecified), PERCOCET, calcium (unspecified), multi vitamin, albuterol, SPIRIVA, "ALIST", tuberculin purified protein derivative (PPD) and ADVAIR. The patient did not have any problems after receiving the first dose of GARDASIL. On 08-JUN-2010, in the morning, the patient was vaccinated IM with her second 0.5 ml dose of GARDASIL (lot # 662765/0821Y) in her right arm. The patient had the impression that the nurse gave her the second dose of GARDASIL at a higher location than the location of the first dose. In the afternoon, the patient received PPD in her left forearm. On 08-JUN-2010 the patient experienced tingling and numbness of the entire right arm and pain on the entire right arm. It was pretty uncomfortable. The patient sought medical attention by an office visit and telephone calls. At the time of the report, the tingling and numbness persisted. No laboratory or diagnostic studies were performed. The reporting physician considered tingling, pain and numbness on the entire right arm to be disabling. Additional information has been requested.

Other Meds: PERCOCET; albuterol; calcium (unspecified); ADVAIR; SPIRIVA; tuberculin purified protein; vitamin D (unspecified); vitamins (unspecified)

Lab Data: None

History: Influenza immunisation

Prex Illness: Alpha-1 anti-trypsin deficiency; Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392256-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	05-Mar-2010	01-Jun-2010	88	07-Jul-2010	08-Jul-2010	FR	WAES1007USA00121	09-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female who on 05-SEP-2009 was vaccinated with the first dose of GARDASIL. On 05-MAR-2010 the patient was vaccinated with the third dose of GARDASIL 0.5ml syringe IM. Three month after vaccination, in June 2010, the patient took test pap smear and the test found high risk HPV NS2 and displasia. At the time of this report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, ??Jun10, high risk HPV NS2 and displasia

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **392258-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Apr-2010	Unknown		07-Jul-2010	08-Jul-2010	FR	WAES1006TWN00118	09-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Migraine, Oculogyric crisis, Tremor

Symptom Text: Information has been received from an agency concerning a 14 year old female who on 23-APR-2010 was vaccinated IM with the 1st dose of GARDASIL through a public vaccination fund. In April 2010, after vaccination, the patient experienced abdominal pain. From April 2010 to JUNE 2010, the patient felt abdominal pain intermittently but without going to visit doctor. On 21-JUN-2010 the patient experienced tremor and oculogyric crisis and was hospitalized. The doctor diagnosed the patient with Abdominal Migraine and thought abdominal pain, tremor and oculogyric crisis were related to Abdominal Migraine and not related to therapy with GARDASIL on 23-JUN-2010. However, the parents felt abdominal pain, tremor and oculogyric crisis were related to the therapy with GARDASIL. The doctor treated patient with some medicine and the patient recovered from tremor and oculogyric crisis on 23-JUN-2010, but the abdominal pain still persisted. Follow-up call has been conducted on 30-JUN-2010. The patient was still hospitalized and the abdominal pain still persisted. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **392275-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Jun-2010	23-Jun-2010	0	07-Jul-2010	12-Jul-2010	NY		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0294Y	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Loss of consciousness, Postictal state, Syncope, Vomiting

Symptom Text: 5 min. after receiving vaccines patient syncopized and had loss of consciousness for about 5 s. Awoke briefly and then had 5-10s of seizure like activity. Patient was then post ictal and vomited x 1. Office called ambulance. Patient was reexamined and fingerstick done.

Other Meds: None

Lab Data: FS 146

History: None - although mother admitted after event pt had seizure like activity after dental procedure.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392291-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Apr-2009	16-Apr-2009	0	07-Jul-2010	13-Jul-2010	MD		13-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	112623AA	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B031AB	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1311Y	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1741Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: Swelling, redness and arm hot to touch at injection site (GARDASIL) the evening of receiving the vaccine.

Other Meds:

Lab Data:

History: Seasonal allergies

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392411-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Jun-2010	29-Jun-2010	0	08-Jul-2010	14-Jul-2010	OH		19-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1354Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3464AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3052AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0087Z	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Malaise

Symptom Text: CC: Nausea, H/A, dizzy. 6/29/10 22:19 presented to ER "not feeling well" ROS - c/o weakness E.D. Dx generalized weakness status post immunizations. Pt received req. immunizations with 9d appoint. ER consulted Peds hospitalist and ok'd to DC home - stable - 7/1 Phoned better per mom.

Other Meds: 11/06 PPD

Lab Data: None listed

History: Saw urology 10-06; No longer sees per dad; 1/08 dietary consult wt. control; 8-31-07 new to office.

Prex Illness: No complaints; WCC

Prex Vax Illns:

Vaers Id: **392431-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	Unknown	Unknown		08-Jul-2010	09-Jul-2010	--	WAES1006USA04079B1	09-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anal atresia, Congenital anomaly, Drug exposure during pregnancy, Gastrointestinal disorder, Oesophageal fistula

Symptom Text: Information has been received from a consumer who on an unspecified date was inadvertently vaccinated with the third dose GARDASIL while pregnant. The mother reported that her male child throat was not connected to his stomach, had an esophageal fistula and had imperforated anus. At the time of the report, the outcome of the events was unknown. Upon internal review, throat was not connected to his stomach, esophageal fistula and imperforated anus were considered to be congenital anomalies. The mother's experience is captured in WAES 1006USA04079. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **392432-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	30-Jun-2010	30-Jun-2010	0	08-Jul-2010	09-Jul-2010	CA	WAES1007USA00010	09-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	IPV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0819Y	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Grand mal convulsion, Syncope

Symptom Text: Information has been received from a physician concerning an 11 year old female who on 30-JUN-2010 was vaccinated with the first dose of GARDASIL (Lot# 663558/0819Y). Concomitant therapy included MENACTRA and unspecified poliovirus vaccine both on 30-JUN-2010. On 30-JUN-2010 the patient experienced an episode of full syncope with tonic-clonic seizure. The symptoms lasted 30 seconds. There was no lab or diagnostic test performed. The patient had sought medical attention in the physician's office and fully recovered there. Upon internal review, the syncope with tonic-clonic seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **392433-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Feb-2008	01-Sep-2008	195	08-Jul-2010	09-Jul-2010	FR	WAES1007USA00237	09-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Asthenia, Fatigue, Laboratory test normal, No reaction on previous exposure to drug, Pain, Pyrexia, Vulval ulceration

Symptom Text: Case received from a health care professional. A psychiatrist reported that her 15 year old daughter was vaccinated with a third dose of GARDASIL (lot# not reported) on 19-FEB-2008. After vaccination the patient experienced recurring phase with pain in the whole body, adynamia, exhaustion, abdominal discomfort and fever. In September 2008 and again on 04-JAN-2010, the patient experienced an ulcus vulvae acutum. To date all diagnostics (unspecified) showed no pathological findings. Previous doses of GARDASIL were given on 26-JUL-2007 (D1) and 02-OCT-2007 (D2) were well tolerated. The patient's adverse experiences were considered to be other important medical event by the reporter. Other business partners included: E2010-03985. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392446-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	06-Jul-2010	07-Jul-2010	1	08-Jul-2010	09-Jul-2010	TX		10-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0318Z	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3437AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B040BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site cellulitis, Injection site erythema, Injection site mass, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Injection site was red and swollen with hard lump underneath skin. Arm was hot and painful to touch at left deltoid area. Diagnosis of cellulitis. Patient treated with Bactrim PO.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392463-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Jul-2010	08-Jul-2010	0	08-Jul-2010	12-Jul-2010	KS		14-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0416Z	0	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B040BA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0318Z	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3067AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: 07/08/2010 mild other. Patient received TDAP, MENACTRA, HEP A, and HPV vaccine today. Had nausea/vomiting within 5 minutes of injections.

Other Meds:

Lab Data:

History: History of chicken pox

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392468-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Jun-2010	25-Jun-2010	0	08-Jul-2010	14-Jul-2010	CA		23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Syncope, Tremor

Symptom Text: The third IPV given on 06/25/10 at about 12 pm, within about 1 minutes after the shot the patient fainted and fell on the floor, but with a support of the MA who gave the shot; pt. shook body 1 time. The pulse is well palpable and woke up within 1 minute. O2 was given 2 liters/min and patient completely woke up within seconds, then became alert well responsive pink BP is stable.

Other Meds:

Lab Data: No

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392469-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Jun-2010	25-Jun-2010	0	08-Jul-2010	14-Jul-2010	CA		23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Posture abnormal

Symptom Text: The HPV (Third HPV) given at about 12:05 pm 06/25/10, about 10 minutes later, patient felt dizzy, head nodded down, but still responsive, not falling, after resting in bed and O2 2 liters given, patient feels well, alert, VS stable.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392492-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Jun-2010	09-Jun-2010	0	08-Jul-2010	09-Jul-2010	TX		23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB402AA	2	Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP055AA	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3076AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	3	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Client administered Hep A adult vaccine should have received Hep A pediatric dose. (Medication error).

Other Meds: No

Lab Data: None

History: No

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392537-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Dec-2009	Unknown		09-Jul-2010	12-Jul-2010	IL		30-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0558X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Soon after receiving the vaccination my daughter has had 3 plantar warts. GARDASIL shots x 3 Lot # 0558X, June 17, 2009, Aug. 19, 2009, Dec 26, 2009.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392542-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	M	09-Jul-2010	09-Jul-2010	0	09-Jul-2010	09-Jul-2010	OH		10-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB349BA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1748Y	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	1487U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: Client had finished with the immunizations being given. He walked out of the exam room with his mother and stopped at the station to receive updated records when he told his mother that he was dizzy. He was hanging onto his mother when he passed out. He was assisted to the floor by both his mother and phn. Jacket was place under his head and feet were elevated in a chair. Ice pack was then applied to the back of his neck. After a few minutes, the dizziness cleared enough for client to sit up and place his back against the wall. He was given orange juice to sip on. He was then assisted up to sit in a chair. Once dizziness completly passed, client did stand at the chair. No dizziness reoccured and client with his mother did go out into the waiting room and again sat for another 10 minutes, then left the facility. Client was fully recovered.

Other Meds:

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392555-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	30-Jun-2010	30-Jun-2010	0	09-Jul-2010	12-Jul-2010	PA		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood calcium normal, Blood thyroid stimulating hormone, Dyskinesia, Liver function test normal, Metabolic function test normal, Myoclonus

Symptom Text: Myoclonic jerks and involuntary movements with a few hours of receiving Gardasil and DPT vaccines at her PCP office. Seen in ER on 6/30 and received Ativan, Benadryl, fluids. Seen in my neurology clinic 7/2 with some residual involuntary movements of the right hand and arm. Bloodwork on 6/30 (BMP, LFTs, TSH, Calcium) was normal. I ordered CPK and Brain MRI 7/2 (but not completed as of today).

Other Meds: Lutera (birth control pills)

Lab Data: see above

History: prior hx of abnormal PAP allergies to SULFA, DEMEROL

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392598-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Jul-2010	10-Jul-2010	0	12-Jul-2010	14-Jul-2010	IL		15-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	2	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3336AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope x 30 seconds.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **392626-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		12-Jul-2010	13-Jul-2010	IL	WAES1007USA00338	13-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Blood test, Headache, Influenza like illness, Menorrhagia, Pain

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female with a history of caesarean section (about 3 years ago) and with no reactions/allergies who was vaccinated intramuscularly with three doses of GARDASIL (therapy start date was reported as July 2009 and third dose on in the middle of June). Concomitant therapy included PROVERA. After being administered GARDASIL in all three of her dosages, in July 2009 the patient experienced flu-like symptoms. She experienced pain in her body, back and had lingering headaches. She also bled profusely during her menstrual after being administered her third shot on approximately 15-JUN-2010. The patient went to emergency room (ER) on several occasions and had blood work done in the ER after being administered her first shot. The patient was hospitalized on an unspecified date. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: PROVERA

Lab Data: Unknown

History: Caesarean section

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392651-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jun-2010	01-Jul-2010	2	12-Jul-2010	14-Jul-2010	MA		15-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1333Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Erythema, Nausea, Oedema peripheral

Symptom Text: Patient started with redness and swelling on LA after receiving the 3rd dose of GARDASIL vaccine. On 7/2/10 pt. started with symptoms of nausea and dizziness. Pt was seen in office on 7/2/10 and EKG was ordered.

Other Meds: None

Lab Data: EKG

History: Allergies to Amoxicillin and Zithromax: rx rash

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392652-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	12-Apr-2010	12-Apr-2010	0	12-Jul-2010	14-Jul-2010	LA	LA100701	23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mobility decreased, Muscular weakness, Nausea

Symptom Text: Developed nausea and muscle weakness on the day about 2-3 hrs. after vaccine was given. Had muscle weakness in lower legs X 4 days and could not climb stairs to her apartment.

Other Meds: Given DMPA injection also - same date.

Lab Data: None done

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392653-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Jul-2010	07-Jul-2010	0	12-Jul-2010	14-Jul-2010	AZ		15-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U3075AA	1	Right arm	Unknown	
VARCEL	MERCK & CO. INC.	1593Y	2	Unknown	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB362AA	2	Left arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Malaise, Pallor

Symptom Text: Immediately after last injection of HPV, client became pale, and stated "I don't feel well". We placed client in supine position. Clients BP was 112/78, 10 min later stated I feel better". Sitting BP was 110/78.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392660-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	18-Mar-2008		12-Jul-2010	15-Jul-2010	--		15-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse reaction, Pain, Pain in extremity, Similar reaction on previous exposure to drug

Symptom Text: My daughter had a severe reaction to her first GARDASIL injection, but she had a flu shot the same day, so we thought she was reacting to that....achy, burning pain up and down her arms and legs. 2 months later she had her second GARDASIL injection and had a similar, but more severe reaction. She begged me to cut her arms off because the pain was so bad, and she said that each arm felt like it weighed 1500 pounds! She is normally a pain-tolerant teenager and not whiny about a little pain, so I knew it was a major deal. We are not planning to get the 3rd injection, as I have no intention of seeing her go through that, or worse, again! Her symptoms only lasted 24 hours.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392665-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Jul-2010	12-Jul-2010	0	12-Jul-2010	13-Jul-2010	NC		13-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1232Y	0	Right arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U3090AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	1	Left arm	Intramuscular	
MMR	MERCK & CO. INC.	1059Y	2	Right arm	Subcutaneously	
IPV	SANOFI PASTEUR	D04132	0	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0652X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB359CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Cold sweat, Dizziness

Symptom Text: Patient administered age appropriate vaccine and after receiving vaccines had felt weak, dizzy and clammy. Client's head brought down to knees. Client fanned and cold compress applied to neck and facial areas. Client offered crackers and juice. Verbalized feeling better after treatment.

Other Meds:

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **392674-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jul-2010	08-Jul-2010	7	12-Jul-2010	13-Jul-2010	HI		27-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1354Y	1	Left arm	Intramuscular	HEPA HPV4 MNQ TDAP

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Areflexia, Guillain-Barre syndrome, Hypoaesthesia, Muscular weakness, Paraesthesia, Paralysis

Symptom Text: Sudden onset of lower leg weakness bilateral with numbness and absent DTR's in lower extremities occurred while awaiting to dance hula in a hotel, was taken to hospital 7/8-9/10 observation overnight, discharge the fd - AM walking. FHX - Father with viral illness contact with daughter x 2 days. The following information was obtained through follow-up and/or provided by the government. 07/13/10. ER visit on 07/08/10-07/09/10. Pt p/w LE weakness and paresthesias and kept for observation. Impression: BLE weakness and paresthesias. 07/13/10. PCP visit on 07/09/10. Strength was coming back in legs. Pt had good reflexes. No sensory deficits. Assessment: s/p LE palsy, transient GBS.

Other Meds:

Lab Data: CT scan head - Normal; CMP = Normal. Drug screen - Neg.; HCG Neg.; CBC - WBC 7.3; H/H 12.9/36.7; Plate 347; N 49; L 43; M 7

History: None The following information was obtained through follow-up and/or provided by the government. DX studies: CT of brain negative.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392685-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Jun-2010	15-Jun-2010	0	12-Jul-2010	14-Jul-2010	ID		23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3250AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1013Y		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3047AA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Skin discolouration

Symptom Text: C/o dark spot on (R) arm after immunizations 3 wks ago on 6/15/10. States initially no fever, blister, redness or swelling. States child c/o sl. itching problem #1 other dyschromia (R) bicep.

Other Meds:

Lab Data:

History: NKA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392687-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Jul-2010	09-Jul-2010	0	12-Jul-2010	14-Jul-2010	MD		23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB408AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1446Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3074AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Approx 15 min after receiving vaccines pt became faint and went to knees we laid her down, checked blood pressure, gave water, she recovered in 10 - 15 minutes.

Other Meds:

Lab Data:

History: None

Prex Illness: Skipped lunch

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392717-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		13-Jul-2010	14-Jul-2010	--	WAES1007USA00325	14-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a physician concerning one of her patient's parents who heard that a female patient, on an unspecified date, received a dose of GARDASIL injection (Lot#: not reported) and she became paralyzed. The physician stated that it was not one of her patients. The outcome of the patient was not reported. Paralysis was considered to be disabling. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **392719-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Jul-2008	10-Jul-2008	7	13-Jul-2010	14-Jul-2010	FR	WAES1007USA00408	14-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Herpes zoster

Symptom Text: Information has been received from Health Authority under reference number: 2010-01832. A 15 year old female patient adolescent with no pertinent medical history reported who on 03-JUL-2008, received a first dose of GARDASIL (batch number and site of administration not reported), via intramuscular route. On 10-JUL-2010, one week after vaccination, the patient presented with shoulder and right shoulder blade herpes zoster. The outcome was favorable with 7 days of valacyclovir hydrochloride. The outcome was recovered on 17-JUL-2008. The literature search on line and in large data base did not reveal any association or relationship between the administration of GARDASIL and the occurrence of herpes zoster. Given the timelines, the imputability of GARDASIL in development of herpes zoster was possible. Health Authority consider as seriousness criteria as "other medically confirmed". Moreover, an inconsistency in the age of patient was identified as Health Authority has reported 15 years but in the narrative the age was reported as 17 years. A request was performed to clarify the age. Other business partner numbers include E2010-04050. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **392747-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Jul-2010	08-Jul-2010	0	13-Jul-2010	15-Jul-2010	OH		15-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB362BA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3055AA	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B047EA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Musculoskeletal stiffness, Unresponsive to stimuli, Urinary incontinence

Symptom Text: Pt received HPV, then Tdap, then Hep A - before last IM MENACTRA was given - Pt stiffened, had stiffening of legs, eyes closed, unresponsive - had mouth movements, then urinated. Given whiff of ammonia with much result, after approx 2 minutes pt became responsive.

Other Meds: None

Lab Data: No Hx of service; No hx of problems with vaccines

History: None

Prex Illness: None; Here for PE

Prex Vax Illns:

Vaers Id: **392749-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Jul-2010	01-Jul-2010	0	13-Jul-2010	15-Jul-2010	IA		15-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	U2937DA	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3473AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0229X	1	Right arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB772DA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Injection site inflammation, Injection site pain, Nausea

Symptom Text: Increase temp 101 >. Sore/inflammation to inj site. Nausea.

Other Meds:

Lab Data: None

History: Juvenile diabetes mellitus; Hypothyroidism

Prex Illness: Non-Known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392757-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	07-Jul-2010	07-Jul-2010	0	13-Jul-2010	13-Jul-2010	FL		23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	U3052BA	0	Left arm	Intramuscular	
	TYP	SANOFI PASTEUR	D0412	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1377Y	0	Right arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP109AA	0	Right arm	Intramuscular	
	ANTH	EMERGENT BIOSOLUTIONS	FAV238	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Feeling abnormal, Feeling hot, Flushing, Gaze palsy

Symptom Text: Patient received shots the became "hot" appr. 3 minutes post-vaccinations. She stated her "head was cloudy" then she became flush, eyes rolled back, and began convulsing.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness: No

Prex Vax Illns:

Vaers Id: **392762-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Jun-2008	24-Aug-2008	73	13-Jul-2010	14-Jul-2010	FR		14-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	N643220	1	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Chemotherapy, Hodgkins disease, Radiotherapy

Symptom Text: Hodgkins lymphoma, she had chemotherapic treatment for 4 months + radiotherapic treatment in 16 sessions.

Other Meds: nothing of medication before this moment

Lab Data: Biopsy test about lymphatic ganglion in August 2008. The patient was vaccinated in 2 times of the Gardasil, the 1§ in 06/12/2008 and the 2§ time in 08/07/2008. She never received the 3§ doses. The patient has to continue her control all the

History: no, nothing.

Prex Illness: no, nothing

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392815-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	22-Mar-2010	22-Mar-2010	0	13-Jul-2010	15-Jul-2010	MA		15-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0968Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt fainted after receiving her 1st GARDASIL vaccine. She recovered without incident after remaining in a recumbent position X several minutes, and drinking some juice.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392838-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Apr-2010	30-Apr-2010	0	14-Jul-2010	15-Jul-2010	FR	WAES1007USA00619	15-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Pain, Pyrexia, Somnolence

Symptom Text: Initial information received by the foreign health authority (reference number ES-AGEMED-522493341) on 02-JUL-2010 regarding a 14 year old female who was administered on 30-APR-2010 a dose of GARDASIL (Lot number not reported), by intramuscular route (site of administration not reported). It was reported that on the same day of administration, on 30-APR-2010, the patient suffered fever, general body pain and somnolence. She recovered from fever and somnolence on the same day. She recovered from body pain one month later, on 30-MAY-2010. It was reported that the general body pain prevented her to do her usual physical exercise during that month. The health authority report, somnolence, general body pain and fever were coded. According to the health authority report, the patient took TERMALGIN, start and stop dates were not reported, to treat the fever. Case reported serious by the health authority with other important medical condition as criteria. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392855-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jun-2010	16-Jun-2010	2	14-Jul-2010	15-Jul-2010	WV	WAES1007USA00541	15-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487Y	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Facial palsy, Speech disorder

Symptom Text: Information has been received from a physician and a licensed practical nurse concerning a 12 year old female with attention deficit/hyperactivity disorder and no known drug allergies, who on 14-JUN-2010 was vaccinated with the first dose of GARDASIL (lot # 1487Y). Concomitant therapy included VYVANSE (for the attention deficit/hyperactivity disorder). No other vaccines were given on the day GARDASIL was administered. On 16-JUN-2010, the patient demonstrated symptoms of facial droop and impaired speech, so went to the ER (not admitted), and was diagnosed with bell's palsy made based on symptoms. No diagnostic testing was performed. The patient was ordered oral ACYCLOVIR, oral PREDNISONE, and ophthalmic erythromycin ointment for 10 days. The patient went to follow-up with an ENT physician (no details). The patient was seen in office on 21-JUN-2010 and 06-JUL-2010, and was still recovering. The event was considered disabling, but not life threatening by the licensed practical nurse. Additional information has been requested.

Other Meds: Vyvanse

Lab Data: None

History:

Prex Illness: Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vaers Id: **392856-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	25-Jun-2007	Unknown		14-Jul-2010	15-Jul-2010	FR	WAES1007USA00607	15-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0902F	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervix carcinoma stage 0, Papilloma viral infection, Vaccine breakthrough infection

Symptom Text: Information has been received from a health care professional on 28-JUN-2010 (phone call of the reporter) and additional information on 05-JUL-2010 (reporting form). The patient was a major smoker (10 cigarettes a day). A gynaecologist reported that a female smoker (10 cigarettes a day) received a complete vaccination series with three doses of GARDASIL IM into the upper arm at the age of 16 years on 25-JUN-2007 (D1, Lot: 654884/0902F, Batch: NE24240), on 24-AUG-2007 (D2, Lot: 1339F, Batch: NF23310) and 19-DEC-2009 (D3, Lot: 0276U, Batch: NF58550). Concomitant therapy included hormonal contraceptives (unspecified). Approximately in DEC-2007 the patient had her first sexual intercourse. In MAR-2010 a cervical pap smear showed PAP IIID. ON 15-JUN-2010 a cervical pap smear PAP IVa and HPV test was positive for high risk type HPV 16. On 15-JUN-2010 conization was performed. Histological result showed a carcinoma in situ of the cervix which was excised in sano. The patient completely within an unspecified time. Vaccination breakthrough was concluded for HPV 16. The case was considered as serious due to additional information on 05-JUL-2010 which included the diagnosis of a carcinoma in situ of the cervix. The event was considered to be an other important medical event. The case was closed. Other business partner numbers include E201003960. No further information is available.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Cervical smear, ??Mar10, cervical pap smear showed PAP IIID; cervical smear, 15Jun10, cervical pap smear showed PAP IVa; diagnostic laboratory test, 15Jun10, HPV test was positive for high risk type HPV 16; diagnostic pathological examinati

History:

Prex Illness: Smoker

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392859-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	13-May-2010	13-May-2010	0	14-Jul-2010	15-Jul-2010	NY		15-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1317Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Pharyngeal oedema, Respiratory distress

Symptom Text: Patient developed localized swelling, redness and pain at injection site followed by throat swelling and respiratory distress.

Other Meds:

Lab Data:

History:

Prex Illness: no

Prex Vax Illns:

Vaers Id: **392873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Jul-2010	11-Jul-2010	2	14-Jul-2010	15-Jul-2010	MI		02-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3052AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Received Tdap (ADACEL) 7/9/10 on 7/11/10 noticed quarter sized reddened area where given (L) deltoid.

Other Meds:

Lab Data: Went to ER as swelling was increased given KEFLEX and BENADRYL

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **392895-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Jun-2010	17-Jun-2010	0	15-Jul-2010	15-Jul-2010	NJ		15-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3028AA	1	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2865AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1099Y	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB311BA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Crying, Syncope, Unresponsive to stimuli

Symptom Text: Patient had a syncopal attack after administration of the HPV vaccine. She was unresponsive and was immediately placed in the supine position with legs raised and cold towels were placed on the head. She was aroused and was crying. She did not have a headache and did not vomit. She was observed for 15 minutes more and then was able to walk out of the office and was feeling alright.

Other Meds:

Lab Data: None.

History: History of syncope with negative work-up in March of 2008.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392897-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Apr-2009	03-Mar-2009	-38	15-Jul-2010	16-Jul-2010	--	WAES0906USA01711	16-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breech presentation, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician's assistant for the pregnancy Registry for GARDASIL, concerning a female patient with no pertinent medical history or no known drug allergies, who on 10-APR-2009 was vaccinated with the first dose of GARDASIL (lot not reported). The patient was pregnant, her LMP was on 03-MAR-2009 (reported as 12 weeks and 6 days of gestation), her EDD: 08-DEC-2009. The patient underwent prenatal blood work (results not reported) and was taking prenatal medication. Follow up information has been received from a physician assistant who reported that the patient delivered a healthy female on 12-SEP-2009 at 37 +3 weeks EGA (estimated gestational age). The patient had had an unplanned primary cesarean section secondary to fetal breech position. The baby's Apgar scores were 8 and 9 at 1 and 5 min. respectively, and weighed 3089 grams. It was reported that the mother did fine postoperatively and fully recovered. Both she and the baby were discharged home together 2 days postpartum. The mother was seen in the office at 2 weeks postpartum for an incision-postpartum check and "everything was fine." Upon internal review primary cesarean section secondary to fetal breech position was considered to be as other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: hematology; Apgar score, 8 and 9 at 1 and 5 min

History:

Prex Illness: Pregnancy NOS (LMP = 3/3/2009)

Prex Vax Illns:

Vaers Id: **392901-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	10-May-2010	10-May-2010	0	15-Jul-2010	16-Jul-2010	FR	WAES1007BRA00014	16-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug interaction, Viral infection

Symptom Text: Information has been received from a consumer concerning her daughter a female who on 10-MAY-2010 was vaccinated with influenza virus vaccine (unspecified) and H1N1. During the vaccination the patient's father told to the nurse who was administering the vaccine that her daughter was supposed to receive the first dose of GARDASIL in the next month. However the nurse recommended the patient should take the vaccine on the same day and she did it. After reading the product label the patient's father considered that occurred a drug interaction between the vaccines. On approximately 10-JUN-2010 the patient experienced viral infection and was hospitalized. On approximately 13-JUN-2010 the patient was discharged from hospital fully recovered from viral infection. No further information is available.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **392903-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jul-2010	16-Jul-2010	FR	WAES1007NOR00005	16-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure before pregnancy, Foetal disorder

Symptom Text: Information has been received from an investigator concerning a female who entered a study. The patient was vaccinated with GARDASIL. After study discontinuation the patient became pregnant. The patient experienced a spontaneous abortion. The fetus had malformations (thumbs pointing inwards). The mother of the patient contacted the investigator and expressed concerns that the abortion and malformations may be due to the vaccination in the trial. The investigator did not express any opinion whether the abortion and malformation were related to vaccine. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392916-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	06-Jul-2010	07-Jul-2010	1	15-Jul-2010	15-Jul-2010	IL		17-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C3438AA		Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0164Z	1	Right arm	Subcutaneously	
HEPA	MERCK & CO. INC.	05682	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0249Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site warmth

Symptom Text: Reported on 7-7-10 that site was very red, warm, and hard - Advised to apply ice and give Ibuprofen. Called again on 7-8-10 to report the same symptoms - Advised to come for appt. on 7-9-10 and cont. ice and Ibuprofen. Exam on 7-9-10 showed redness at site - 5cm. diam. - Cont. ice, MORTIN, and BENADRYL PRN.

Other Meds:

Lab Data:

History:

Prex Illness: 6th grade physical

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392960-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-Jul-2010	15-Jul-2010	2	15-Jul-2010	16-Jul-2010	IL		16-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	00952	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1013Y	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3356AA	5	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	16544	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site mass

Symptom Text: Pt's mother called office today - pt. has redness and lump at immunization site - Mom applying ice and giving pt. ibuprofen - Reaction to VARIVAX.

Other Meds:

Lab Data:

History:

Prex Illness: School Physical

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **392978-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Apr-2010	23-Apr-2010	0	16-Jul-2010	16-Jul-2010	CT		18-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Visual impairment

Symptom Text: Child c/o "funny vision" from (R) eye, severe headache and dizziness approximately 4-5 hours after receiving GARDASIL #1 on 4/23/10 no treatment. We were informed of this 2 months afterwards when child came for #2 GARDASIL.

Other Meds: none

Lab Data: none

History: migraine headaches

Prex Illness: none

Prex Vax Illns:

Vaers Id: **392979-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	M	Unknown	27-Aug-2008		16-Jul-2010	19-Jul-2010	OK	WAES0807USA04408B1	02-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Atrial septal defect, Developmental delay, Drug exposure during pregnancy, Echocardiogram normal, Failure to thrive, Foetal distress syndrome, Gastrooesophageal reflux disease, Neonatal tachycardia, Premature baby, Weight gain poor

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a male baby's 24 year old mother with anxiety and depression and no known allergies who on 15-OCT-2007 was vaccinated with the first dose of GARDASIL. On 14-JAN-2008 she was vaccinated intramuscularly with the second 0,5 ml dose of GARDASIL (lot no. 659055/1522U). Concomitant therapy included WELLBUTRIN. Her LMP was 07-JAN-2008. Due date was 13-OCT-2008. On approximately 17-AUG-2008 the mother delivered a baby boy "at around 32 weeks gestation, almost two months early". The physician did not remember exactly and did not have the patient's chart at her immediate disposal. The physician also followed the baby in her practice. The physician reported "he was now around nine months old and weighed around 15 pounds. He had some failure to thrive issues and had some developmental delays". No further information was provided at this time. Follow-up information received from the physician concerning that the mother had experienced prolonged premature rupture of membranes and was given intravenous PITOCIN and steroids for the baby since less that 34 weeks gestation. The baby had fetal distress in labor which the physician thought was not surprising given the age and loss of amniotic fluid, but she delivered vaginally on 27-AUG-2008, at 32+2 weeks gestation (her EDD was 13-OCT-2008). The baby had a patent foramen ovale, "which is now almost gone", and tachycardia for which he was followed by a pediatric cardiologist. "We are not worried about this though", The most concerning problem the baby had was his weight gain. The physician saw him in Mid-Jun and he only weighed 15LBS, and he was having some reflux problems for which he was sent to a pediatric gastroenterologist. The physician read from a form that the pediatric gastroenterologist consult dated 19-Mar-2009 which noted the baby was seen for his atrial-septal defect/patent foramen ovale, which was almost gone, and he had a normal echocardiogram, with recommended followed

Other Meds: WELLBUTRIN; ZOLOFT

Lab Data: Unknown

History:

Prex Illness: Anxiety; Depression

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393017-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2010	01-Jul-2010	0	16-Jul-2010	19-Jul-2010	CO		19-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain in extremity, Sensation of heaviness

Symptom Text: Very sore arm with feeling of heaviness in upper arm that has lasted over 2 weeks after imm.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393019-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Jul-2010	15-Jul-2010	0	16-Jul-2010	19-Jul-2010	CA		19-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C3438AA	0	Left arm	Intramuscular	
MEN	SANOFI PASTEUR	U3061AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1354Y	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1437Y	0	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted for about 20 seconds in waiting room as she walked out, father was able to break fall, no injuries reported by patient or visible injuries, patient was brought back to treatment room, vitals were obtained and normal, patient was released and self ambulated to vehicle.

Other Meds:

Lab Data:

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393021-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Jul-2010	16-Jul-2010	0	16-Jul-2010	19-Jul-2010	NC		19-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1377Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Oedema peripheral

Symptom Text: Hurting at injection site then arm swelling from shoulder to tips of fingers on entire right side of arm per dr 4 tsp liq Benadryl (12.5/5) given at 6:30 PM when pt returned to night clinic ice applied to area.

Other Meds: none known

Lab Data: N/A

History: ADHD & learning disabalities; NKDA

Prex Illness: none known

Prex Vax Illns:

Vaers Id: **393022-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Feb-2010	09-Mar-2010	11	16-Jul-2010	19-Jul-2010	CA		17-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0914X	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Abdominal tenderness, Activities of daily living impaired, Blood pressure increased, Diarrhoea, Dizziness, Fatigue, Headache, Heart rate increased, Lethargy, Malaise, Mood altered, Muscle spasms, Nasal congestion, Paranasal sinus discomfort, Viral infection

Symptom Text: Light headed, dizzy, head ache, general malaise, fatigue, stomach ache. The following information was obtained through follow-up and/or provided by the government. 07/23/10. PCP visit on 02/26/10. Pt received immunization. On 03/16/10, Pt reported being tired, nasal congestion. On exam: increased BP and HR. Assessment: r/o viral illness, lethargy. 03/22/10, Pt reported being sick for 2 wks, upset, HA, cramping, diarrhea. On exam: abdomen tenderness. Assessment: diarrhea, sinus tenderness. On 03/22/10, Pt reported missing school, being sick for 2 wks, upset, HA, cramping, diarrhea

Other Meds:

Lab Data: Blood tests, urine, stool, head and abdomen X-rays. The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: CBC wnl. CRP negative, No virus antibody detected.

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393044-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Jun-2010	22-Jun-2010	0	16-Jul-2010	19-Jul-2010	TX		05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	0	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	C3382AA	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	1233Y	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back injury, Dizziness, Fall, Head injury

Symptom Text: Pt c/o dizzy episode 5-7 min post vaccination. Pt fell and hit head and back. Physical exam at office ok. However, mom took pt to ER for further evaluation. F/u x-ray WNL.

Other Meds:

Lab Data: Radiology x-ray neck/spinal-WNL

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393061-1** **Related reports:** 393061-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	M	15-Jul-2010	15-Jul-2010	0	19-Jul-2010	19-Jul-2010	VA		19-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0450Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Dyskinesia, Immediate post-injection reaction, Loss of consciousness, Nausea, Oxygen saturation normal

Symptom Text: Response immediately following GARDASIL injection. Jerking movements of 4 limbs and loss of consciousness - lasted 30-60 seconds with pt. returning to normal with vague feeling of nausea and confusion as to what had occurred. Pt. re-examined by doctor, VS taken, O2 sat NL. Pt was discharged to home.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **393061-2** **Related reports:** 393061-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	M	15-Jul-2010	15-Jul-2010	0	28-Jul-2010	29-Jul-2010	VA	WAES1007USA02086	29-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0450Z	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dyskinesia, Fall, Immediate post-injection reaction, Loss of consciousness, Nausea, Presyncope

Symptom Text: Information has been received from an office staff member and a physician concerning a 15 year old male patient with no pertinent medical history and no known drug allergies/drug reactions and family history of epilepsy who on 15-JUL-2010 was vaccinated with the first dose of GARDASIL (Lot # 0450Z). It was reported that immediately after receiving GARDASIL the patient experienced jerking movements of four limbs and loss of consciousness which lasted 30-60 seconds. The patient then returned to normal with vague nausea and the patient did not know what happened. The office staff member stated that the patient had his blood pressure taken and his vital signs were fine and the patient was able to go home. The physician confirmed that on 15-JUL-2010 the patient received the first dose of GARDASIL and did not received any concomitant vaccinations. The physician reported that immediately after the patient received the vaccine, the patient fell back and had most likely a short seizure along with a vasovagal response. When the patient regained consciousness he was not postictal but felt nauseous. There were no laboratory diagnostic tests performed. At the time of the report the patient had recovered (on therapy). Upon internal review most likely a short seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **393077-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Jul-2010	15-Jul-2010	1	19-Jul-2010	19-Jul-2010	KS		20-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B047AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3098AA		Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0249Y	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1435Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: 7/16 Presents to HD with redness at of swelling on (R) mid upper arm. 16.5 x 11cm reddened area encircling 6.25 x 7 cm raised area cool pack applied to arm. Advised client's father to notify PCP. Client afebrile. 7/19 decreased s/s.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393091-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Sep-2007	01-Nov-2008	427	19-Jul-2010	20-Jul-2010	FR	WAES1005USA00479	20-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aggression, Grand mal convulsion, Muscle twitching, Myoclonus, Staring

Symptom Text: Information has been received from the father of a now 16 year old female patient who in the fall 2007 began series of GARDASIL which was completed in June 2008. By November 2008, the patient developed twitches in her large muscle, not specified to any muscle (random). On 03-May-2010, the patient hit a boy in the nose. The patient saw a neurologist. At the time of the report the patient's outcome the relation between twitches in her large muscle, hit a boy in the nose and GARDASIL were unknown. Follow up information has been received from the physician who reported that the patient with no preexisting conditions, in June 2008, was vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL in the school. There was no concomitant medication. On an unspecified date, (reported as "5/12"), "after GARDASIL", the patient began developing generalized tonic clonic convulsion or myoclonic jerking with staring episodes. In November 2008, the patient experienced aggressive behavior/hit a boy in the nose. On 01-DEC-2008, the patient experienced twitches in her large muscles. At the time of the report the patient's outcome and the relation between twitches in her large muscle, aggressive behavior/hit a boy in the nose, generalized tonic clonic convulsion or myoclonic jerking with stirring episodes and GARDASIL were unknown. Generalized tonic clonic convulsion was considered to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **393092-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Apr-2009	01-Aug-2009	101	19-Jul-2010	20-Jul-2010	PA	WAES1007USA01051	20-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure before pregnancy, Urinary tract infection

Symptom Text: Information has been received from a physician and gynecologist's office manager, for GARDASIL, a Pregnancy Registry product, concerning an 18 year old female patient with no known drug allergies, who on 22-APR-2009 was vaccinated intramuscularly with the first dose of GARDASIL (lot # not available). On 28-JUL-2009, the patient received the second dose of GARDASIL (lot # not available). In August and September 2009, the patient experienced urinary tract infections. On 23-NOV-2009, when the patient went to receive her third dose, she found out she was pregnant. A urine beta-human chorionic gonadotropin test was performed. The third dose was not given. The patient was referred to a gynecologist. The gynecologist's office manager reported that on 16-DEC-2009, the patient had a therapeutic abortion. The reason for the elective procedure was not specified in the chart. This was the patient's first pregnancy. Last menstrual Period was on 05-OCT-2009. There were no serious criteria (patient "in and out"). The outcome was unknown, as the patient did not return for follow up visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: urine beta-human, 11/23/09, was found out she was pregnant

History:

Prex Illness: pregnancy NOS (LMP = 10/5/2009)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393154-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	13-Jul-2010	17-Jul-2010	4	20-Jul-2010	20-Jul-2010	IA		23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0245Z	1	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3357AA	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3091AA	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1099Y	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Dyspnoea, Rash generalised, Urticaria

Symptom Text: Full body rash with difficulty breathing. Hives waist to thighs et back pt woke up Sat am d/t tightness in chest.

Other Meds: None

Lab Data:

History: PENICILLIN

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393171-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	15-Jul-2010	Unknown		20-Jul-2010	20-Jul-2010	MN		21-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU(H1N1)	SANOFI PASTEUR	UPO16AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1332Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: H1N1 vaccine given to this person by mistake. Vaccine was intended for his sister. No reported adverse effects as of 7/20/10.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393179-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-Jul-2010	20-Jul-2010	0	20-Jul-2010	20-Jul-2010	TX		21-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	U3051CA	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0569Z	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1593Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3043AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Disorientation

Symptom Text: Child became disoriented, described by parent as not knowing where she was, and was hysterically crying. Event lasted about 45 minutes and resolved spontaeously. Child could not explain it afterwards.

Other Meds: none

Lab Data: none

History: none

Prex Illness: cough

Prex Vax Illns:

Vaers Id: **393195-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Jul-2010	20-Jul-2010	1	20-Jul-2010	21-Jul-2010	VA		21-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0331Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Haematuria, Red blood cell count increased, White blood cell count decreased

Symptom Text: Hematuria 12 hours after receiving GARDASIL dose #2 on 7/19/2010 urinalysis prior to vaccine (7/19-no RBC no WBC) urinalysis 7/20 10-12 RBC/HPF and 20-25 WBC/HPF.

Other Meds: None

Lab Data: Urinalysis 1.025/pH 6.0/protein 1+/tr ketone/occ blood tr

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **393227-1** **Related reports:** 393227-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	15-Jul-2010	15-Jul-2010	0	21-Jul-2010	21-Jul-2010	VA		21-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C3353AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Trendelenburg position

Symptom Text: After client complained feeling lightheaded approx 3 min after receiving vaccines. Client became pale - did not lose consciousness. Client placed in Trendlenberg position and ice pack applied to forehead. Client offered apple juice and consumed by client. Client monitored 15 minutes and discharged from clinic ambulatory to home with mother.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393227-2** **Related reports:** 393227-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	15-Jul-2010	15-Jul-2010	0	21-Jul-2010	22-Jul-2010	VA	VA10011	26-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB336BA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3353AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Trendelenburg position

Symptom Text: Client complained of feeling lightheaded approx. 3 min after receiving vaccines. Client became pale - did not lose consciousness. Client placed in Trendlenberg position and ice pack applied to forehead. Client offered apple juice and consumed by client. Client monitored 15 min and discharged from clinic ambulatory to home with mother.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **393228-1** **Related reports:** 393228-2; 393228-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	M	15-Jul-2010	15-Jul-2010	0	21-Jul-2010	23-Jul-2010	VA		10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	TDAP
	MNQ	SANOFI PASTEUR	U3029AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Trendelenburg position

Symptom Text: Approximately 3 minutes after receiving vaccine, client complained of feeling light headed and was pale. He was assisted into Trendelenberg position. Ice pack placed on forehead, apple juice offered and consumed by client. Did not lose consciousness. Monitored thirty minutes and discharged home-ambulatory. The following information was obtained through follow-up and/or provided by the government. 8/10/10 Pt. did not seek outside medical attention for AE.

Other Meds:

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393228-2** **Related reports:** 393228-1; 393228-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	M	15-Jul-2010	16-Jul-2010	1	21-Jul-2010	21-Jul-2010	VA		21-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Unknown	TDAP
	MNQ	SANOFI PASTEUR	U3029AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Mom called at around 4:00 pm 7/16/10. States she picked her son up from sitter and he has 3" long by 2" wide rash about 1" below where MCV4-P was given 7/15/10. No other complaint states rash has been there several hours.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393228-3** **Related reports:** 393228-1; 393228-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	M	15-Jul-2010	15-Jul-2010	0	21-Jul-2010	22-Jul-2010	VA	VA10012	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3029AA	0	Right arm	Intramuscular	TDAP
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site rash, Pallor, Trendelenburg position

Symptom Text: Approximately 3 min after receiving vaccines, client complained of feeling light headed and was pale. He was assisted into Trendelenberg position. Ice pack placed on forehead, apple juice offered and consumed by client. Did not lose consciousness. Monitored 30 min and discharged home - ambulatory. Mom called at about 4:00 PM 7/16/10. States she picked her son up from sitter and he has a 3" long by 2" wide rash about 1" below where MCV4 was given 7/15. No other complaints. States rash has been there several hours.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393230-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jul-2010	15-Jul-2010	1	21-Jul-2010	21-Jul-2010	TN		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1701Y	1	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3353AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1354Y	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Injection site erythema, Injection site nodule, Injection site swelling, Oedema peripheral

Symptom Text: Mother called reported redness and swelling (L) arm back of (L) arm from armpit to elbow large amt of swelling and redness with hard nodule at varicella injection site to (L) posterior arm.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393235-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	13-Jul-2010	13-Jul-2010	0	21-Jul-2010	21-Jul-2010	ME		21-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0040Z		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3080AA		Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Visual impairment

Symptom Text: About 7 min. after vaccine was given child states seeing black spots in vision and feeling lightheaded. We had child lay down and rest w/feet up.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393242-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Jul-2010	14-Jul-2010	1	21-Jul-2010	21-Jul-2010	TX		22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	07032	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Mother reported that after a day "on the golf course" she fainted and had "seizure like activity" - was not hospitalized, but advised by MD to report to VAERS - (High temperatures & humidity locally).

Other Meds:

Lab Data: None - Pt did not see a doctor

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **393255-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.1	U	Unknown	29-Jul-2008		21-Jul-2010	22-Jul-2010	MI	WAES0809USA04046B1	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Asphyxia, Death, Drug exposure via breast milk

Symptom Text: Information has been received from a physician concerning a 6-8 week old patient whose 25 year old mother on 29-JUL-2009 (conflicting information, also reported as two days post-partum) was vaccinated with her first 0.5 mL dose of GARDASIL (lot# 660391/0063X) in her left deltoid, (it was noted that she was not pregnant when she received the first dose). The patient was breastfeeding. On 31-JUL-2008 the patient's mother was breastfeeding her infant and she fell asleep. Subsequently, the infant died from suffocation and was found in the morning. It was ruled as a smothering injury: "overlay compression asphyxia, mother laid over child". The reporting physician felt that the patient's death was not related to vaccination with GARDASIL. A standard lot check investigation was performed. All in-process quality checks for the lot # 660391/0063X were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center for Biologics Evaluation and Research and was released. The mother's experience has been captured in WAES# 0809USA04046. Additional information has been requested. This report was previously sent to the FDA on 30-SEP-2008 (WAES# 0809USA04046) and was previously split to create a baby report.

Other Meds: Unknown

Lab Data: autopsy, 07/31/08, overlay compression asphyxia

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393257-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.1	M	Unknown	01-Jul-2009		21-Jul-2010	22-Jul-2010	FR	WAES0910USA04217B1	02-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Congenital inguinal hernia, Drug exposure during pregnancy

Symptom Text: Information has been received from a health care professional under the reference number RA-102-2010 and transmitted by the agency. Case linked with the case E2009-10048 (corresponding to mother case, WAES #0910USA04217). A male baby whose mother had received the first and second doses of GARDASIL (batch number not reported) on 30-APR-2009 and 30-JUN-2009 presented an inguinal hernia. The mother became pregnant in July 2009 (exact date not provided). The health care professional reported that a male baby was born on 09-APR-2010. Everything went well during the delivery, mother and baby were in good health conditions. One month after delivery he presented an inguinal hernia and needed to be submitted to a surgery. Inguinal hernia was considered to be a congenital anomaly. The outcome was recovered. The case was closed. Other business partner numbers include E2010-04243.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **393258-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		21-Jul-2010	22-Jul-2010	FR	WAES1007TWN00025	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Cervical dysplasia, Hysterectomy

Symptom Text: Information has been received from a physician concerning a 35 year old female who was vaccinated with 3 doses of GARDASIL in 2009. The patient's cervical smear was normal before vaccination. However, the patient's cervical smear showed abnormal (cervical intraepithelial neoplasia iii) after 3 doses of vaccination. The patient was hospitalized and received laparoscopic assisted vaginal total hysterectomy on 18-Mar-2010. Subsequently, the patient recovered from cervical intraepithelial neoplasia iii. Cervical intraepithelial neoplasia iii was considered to be disabling. No further information is available.

Other Meds: Unknown

Lab Data: Cervical smear, ??09, normal (before vaccination); cervical smear, ??Mar?10, CIN III (after 3 doses of GARDASIL vaccination)

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **393259-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2009	01-Jul-2010	365	21-Jul-2010	22-Jul-2010	UT	WAES1007USA01623	22-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion missed, Drug exposure during pregnancy, Haemorrhage

Symptom Text: Information has been received from a physician for a of GARDASIL a pregnancy registry product, concerning a 17 year old female with convulsion who in approximately July 2009, was vaccinated with the second dose of GARDASIL (Lot # unknown). Concomitant therapy included DEPAKOTE. The physician reported that the patient had received the second dose of GARDASIL. In late May 2010, the patient became pregnant and subsequently, at 8 weeks gestation, experienced bleeding and missed abortion, at which time she visited the emergency room. The physician stated it was unclear if the patient was still on DEPAKOTE during the pregnancy. The reporting physician considered the events bleeding and missed abortion to be other important medical events. Additional information has been requested.

Other Meds: DEPAKOTE

Lab Data: complete blood cell, Normal; serum beta-human, elevated

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Convulsion

Prex Vax Illns:

Vaers Id: **393317-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Jul-2010	13-Jul-2010	1	22-Jul-2010	22-Jul-2010	AR	AR1029	27-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3079AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B052AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0066Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash

Symptom Text: Woke about 3 am itching put anti itch cream, gave ibuprofen and BENADRYL. No itching today. 6 raised area on face 2 on neck rt side right now not itching few areas on both legs around ankles.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393336-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Apr-2009	14-Apr-2009	0	22-Jul-2010	23-Jul-2010	FR	WAES1007POL00004	23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Grand mal convulsion, Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning a 13 year old female with pollen allergy who on 14-APR-2009 was vaccinated with a first dose of GARDASIL. On 14-APR-2009 the patient experienced syncope. The patient quickly returned to consciousness. On 16-JUN-2009 the patient was vaccinated with a second dose of GARDASIL. On 16-JUN-2009 the patient experienced toniclonic convulsion and loss of consciousness. Return to consciousness was slow lasted from 0.5 to 1 minute. Subsequently, the patient recovered from syncope, toniclonic convulsion and loss of consciousness. The reporter felt that syncope, toniclonic convulsion and loss of consciousness were related to therapy with GARDASIL. Toniclonic convulsion and loss of consciousness were considered to be immediately life-threatening. Toniclonic convulsion and loss of consciousness were considered to be an other important medical event by the physician. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pollen allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393337-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Jun-2010	22-Jun-2010	0	22-Jul-2010	23-Jul-2010	FR	WAES1007USA01887	23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ51180	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Hyperhidrosis, Syncope, Tremor, Vomiting

Symptom Text: Case received from Health Authorities under the reference number RA-101-2010 on 12-JUL-2010. A 13 year old female on 22-JUN-2010 was vaccinated IM with the first dose of GARDASIL (Lot# NJ51180, Batch # NM14120). On same day (22-JUN-2010), 15 minutes after the administration, the patient experienced syncope, tremor, sweating and vomiting. No other event was experienced. The reaction stopped in a few seconds, but in the fall the patient hit with her head and x-ray was done but didn't reveal a fracture. The patient had no specific treatment for the event. The outcome was recovered. The case is closed. Syncope, tremor, sweating, vomiting and fall were considered to be other important medical events by the reporter. Other business partner numbers included E2010-04280. No further information is available.

Other Meds: Unknown

Lab Data: X-ray, 22Jun10, didn't reveal a fracture

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393382-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Jul-2010	06-Jul-2010	0	22-Jul-2010	23-Jul-2010	OH		02-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0075Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Syncope

Symptom Text: Syncope episode, lightheaded, pale face. Pt laid down for 15 mins & sat for 5 before leaving office. No treatment needed.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393383-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Jul-2010	22-Jul-2010	0	22-Jul-2010	23-Jul-2010	VT		02-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1333Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: After apx. 5 min after receiving 2nd HPV vaccine pt passed out. Pt rested lying down - cool compress to head. BP immed after passing out 98/54 BP 15 min after resting 106/64.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393403-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Dec-2009	16-Mar-2010	91	22-Jul-2010	23-Jul-2010	CA		23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue

Symptom Text: Fatigue.

Other Meds: none

Lab Data: antibodies negative for EBV, Coxsackie, CMV, enterovirus. CRP, ANA, CBC within normal limits

History: patient reported stuffy nose and bloody noses

Prex Illness: none

Prex Vax Illns:

Vaers Id: **393411-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Jul-2010	22-Jul-2010	1	22-Jul-2010	23-Jul-2010	TX		23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3078AA		Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3249AA		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1205Y		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0216Y		Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB362AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling

Symptom Text: Itchy, red elevated vaccine site. Not painful. Cool compresses and BENADRYL.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **393417-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Jul-2010	20-Jul-2010	0	22-Jul-2010	23-Jul-2010	NV		02-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3337AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	U3035AA	4	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1539Y	0	Right leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: (L) deltoid redness, swelling and pain after immunization local swelling.

Other Meds: TDAP; GARDASIL

Lab Data:

History: None

Prex Illness: Swelling at site

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393434-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Jul-2010	20-Jul-2010	0	23-Jul-2010	23-Jul-2010	CO		02-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1120Y		Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	NULL		Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	NULL		Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3476AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Pallor

Symptom Text: After receiving her 1st HPV, TDAP, Varicella and MCV4, patient asked if she could wait in waiting room for the 15 min time frame (post HPV shot protocol). I said yes. As she was walking out, someone yelled for me as pt became very clammy, pale, & started to faint. (see attached for rest). Pt sat in chair nearby and put head btw her legs. Given juice. Moved back to room with bed & had her wait 15 more minutes. Given more juice and crackers. Left at 1610 PM feeling & looking much better.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393445-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Jul-2010	15-Jul-2010	0	23-Jul-2010	23-Jul-2010	TN		27-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0913Y	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1741Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Injection site urticaria, Injection site warmth

Symptom Text: Pt. came to health dept. 7/16/10 with large 1"x2" wheal on outer upper (R) arm where VARIVAX #2 had been placed on 7/15/10. Area was "hot and swollen". Pt. denied other symptoms at this visit and was advised to use ice pack.

Other Meds: None

Lab Data:

History: NKA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **393455-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	18-Feb-2009	18-Feb-2009	0	23-Jul-2010	23-Jul-2010	OK		11-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U		Left arm	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Dizziness, Joint stiffness, Musculoskeletal stiffness, Nausea, Pain, Swelling

Symptom Text: JOINTS AND MUSCLES STIFFNESS, ACHES, PAINS, SWELLING, DIZZINESS, NAUSEA The following information was obtained through follow-up and/or provided by the government. 8/10/10 Outpatient OB/GYN record received for date of service 2/18/10. Gardasil vaccine given.

Other Meds:

Lab Data: BLOOD TEST - 02/17/2010 - DIAGNOSED WITH LUPUS The following information was obtained through follow-up and/or provided by the government. 7/27/10 Labs received for dates of service 2/17/10. Labs and diagnostics: Lymph % 0.85 (L), Albumin

History: none

Prex Illness: soreness at injection site

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393460-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-Jul-2010	21-Jul-2010	0	23-Jul-2010	23-Jul-2010	VI		27-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1450Y	0	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	03028AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Heart rate irregular, Pulse pressure decreased

Symptom Text: About 10-15 minutes after vaccine, pt c/o dizziness. Skin cool clammy. Pulse irregular and weak. Pulse 80 palpable.

Other Meds:

Lab Data: none. pt placed head in between legs. cold juice given. watched pt in clinic room X 20 minutes until symptoms subsided and bp/pulse regular

History: mother denied

Prex Illness: none

Prex Vax Illns:

Vaers Id: **393482-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Jul-2010	15-Jul-2010	0	23-Jul-2010	23-Jul-2010	WI		23-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1497X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dysstasia, Gait disturbance, Hypoaesthesia, Immediate post-injection reaction, Presyncope

Symptom Text: Initial "numb" feeling in hand immediately after vaccination. Then very quickly developed near-syncope: unable to stand or walk, very dizzy, felt like she would faint. Symptoms lasted about 45 minutes before patient able to walk with assistance out of clinic.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393494-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Jul-2010	23-Jul-2010	0	23-Jul-2010	26-Jul-2010	MA		27-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0318Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Malaise, Moaning, Respiratory rate increased, Vomiting

Symptom Text: Pt counseled about HPV vaccine and consented to injection. Has never received HPV vaccine in the past. No known drug or vaccine allergies. Reported she sometimes feels faint around needles. Pt counseled about side efects including possible pain at insertion site and possibility of feeling faint. Written info given. MA gave injection and after approximetly 20 sec pt stated she felt dizzy and her eyes began to widen. At that point MA brought me back in the room where I was there with the patient and her brotehr and patient was lying on the table making jerking movements of extremities and moaning. I immedietly had the front desk call for an ambulance. After about 1 -2 minutes the patient began to stop moaning and movements ceased. She was breathing heavily but was able to speak and said she felt sick. Her breathing then started to slow to a normal pace and after about another minute she vomitted into a bucket. After about 7 minutes paramedics came. Pt was able to walk to the stretcher with assistance. BP was 93/60. Pt denies any hx of seizure activy, but states she has fainted after vaccinations in the past. Pt brought the emergency room for evaluation. Possible adverse reaction to GARDASIL submitted to the FDA adverse reaction reporting system.

Other Meds: Pt was on Fluoxitine 10 mg daily

Lab Data: BP after sycopy tonic-clonic 93/60

History: No known drug allergies

Prex Illness: Depression/Anxiety

Prex Vax Illns:

Vaers Id: 393517-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	16-Jan-2008	01-Feb-2008	16	26-Jul-2010	26-Jul-2010	WA		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Left arm	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Chemotherapy, Hodgkins disease, Injection site pruritus, Lymphadenopathy, Mass, Pruritus

Symptom Text: Vaccination administered 1/16/08, despite argument with PA and LPN about not getting it (and being told I "may already have the virus," so I should get the vaccination; they obviously believed it was a cure instead of preventative) Severe itching appeared a few weeks after the initial vaccine. Injection site itched slightly after the vaccine was administered, and continued to spread to legs, hips, and buttocks). Itching felt as if it were coming from the inside (subcutaneous). Noticed lumps along collarbone (left side) and went to physician. After a number of physicians, received chest x-ray and needle biopsy, followed by an excisional biopsy, which diagnosed me with Hodgkin's Lymphoma, stage 2A. Treatment: Six months of ABVD chemotherapy (treatment occurred Thursdays, every other week from 06/24/08 to 12/04/08). Patient has been free of symptoms since December 2008. The following information was obtained through follow-up and/or provided by the government. 08/12/10. PCP visits on 01/16/08-06/08/09. On 06/03/09, Pt reported having Hodgkin's disease, unspecified and lymphadenopathy. Also, Pt reported having received chemotherapy and became clean of Hodgkin's disease in 12/08. ROS was negative.

Other Meds:

Lab Data: Needle biopsy 5/2008 Excisional biopsy 5/21/2008 (positive for Hodkin's Lymphoma) Bone marrow biopsy 5/29/2008 (no presence of cancer in bone marrow; therefore, stage 2A) Various pulmonary function tests, etc. The following information was

History: Penicillin allergy. The following information was obtained through follow-up and/or provided by the government. PMH: bcp, varicella, MRSA, Streptococcal septicemia, family h/o CA. Allergies: PCN rash.

Prex Illness: No illness at time of vaccination.

Prex Vax Illns: itching; cancerous lymph nodes~HPV (Gardasil)~1~22.25~Patient

Vaers Id: **393526-1** **Related reports:** 393526-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Jul-2010	23-Jul-2010	0	23-Jul-2010	26-Jul-2010	CA		10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3098AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1013Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Convulsion, Pain

Symptom Text: 1. Seizure lasting about 15-20sec. 2. Generalized weakness. 3. Painful episode.

Other Meds:

Lab Data: Refer to lab work; U/A; CBC; CRP; thyroid panel

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **393526-2** **Related reports:** 393526-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Jul-2010	23-Jul-2010	0	23-Aug-2010	24-Aug-2010	CA	WAES1008USA01984	03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy

Symptom Text: Information has been received from a physician concerning a 16 year old female with no illness and pre-existing medical conditions who on 23-JUL-2010 at 12:15PM was vaccinated IM into her left deltoid with the first dose GARDASIL (lot# 662304/1013Y). On the same day at 12:25 the patient experienced a seizure with convulsion and was her rolling eyes. The event lasted for 7-10 seconds. No medication were given. The patient was referred for Electroencephalogram (EEG). At the time of the report the patient status was unknown. Upon internal review, seizure disorder with convulsion and rolling eyes was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393529-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Jun-2010	Unknown		23-Jul-2010	26-Jul-2010	OR		04-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Injection site nodule, Injection site pain, Nausea, No reaction on previous exposure to drug, Pallor, Presyncope

Symptom Text: Pale, diaphoretic, nauseous, near syncopal within 3 minutes of injection. This passed over the next 10-15 min. No prior hx of similar sx ass'd w/ 1st 2 HPV shots given. Now, 2 wks later, has fibrotic "knot" (tender) in (L) deltoid where shot was administered.

Other Meds: DEPO PROVERA q 3 mo

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **393569-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
33.0	F	Unknown	Unknown		26-Jul-2010	27-Jul-2010	FR	WAES1007TWN00026	28-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Drug exposure before pregnancy, Laser therapy

Symptom Text: Information has been received from a physician concerning a 33 year old female who was vaccinated with 3 doses of GARDASIL intramuscularly. Afterward the patient was pregnant. The patient's physician found the patient had condyloma during suturing after normal delivery. Then the patient received laser intervention to remove condyloma. Subsequently, the patient recovered from condyloma. Condyloma was considered to be an other important medical event by the physician. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **393570-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Aug-2008	Unknown		26-Jul-2010	27-Jul-2010	--	WAES0810USA02499	28-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Flank pain, Premature labour, Uterine contractions during pregnancy

Symptom Text: Information has been received from a consumer concerning her daughter, a 14 year old female who on 08-AUG-2008 was vaccinated with the first dose of GARDASIL, 0.5 mL, intramuscular, The caller stated that when her daughter received the first dose of vaccination she was 2 months pregnant. On 14-OCT-2008, the patient received the second dose of GARDASIL. Caller did not mention any adverse event. It was unknown if the patient sought medical attention. Additional information has been received from a consumer concerning her daughter, who "delivered really early and the baby died after it was born." The consumer stated her daughter was almost five and a half to six months pregnant and she started having pains in her side, went to the doctor and was told everything was ok and went home. The next week her pains started again and then felt like contractions, and when she went to the doctor she was already dilated around four or more centimeters and they couldn't stop her contractions. The consumer reported that the baby was born and then died (No further details provided). It was reported that the consumer's daughter had good days and bad days. The baby's experience is reported in WAES 0810USA02499B1. Upon internal review, preterm delivery was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 6/23/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393571-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	13-Jul-2010	13-Jul-2010	0	26-Jul-2010	27-Jul-2010	TX		29-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0318Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site pain

Symptom Text: Patient complained of feeling light-headed after receiving her third Gardasil dose, was placed in a supine position and observed for 15 minutes, and felt back to normal and was ambulatory upon leaving the office. She called back on 7/26/2010 complaining of persistent pain in her left upper arm since receiving the vaccine and stated the pain was not relieved with Tylenol. She denies erythema or swelling at the injection site, fever, or other complaints. She was advised to try ibuprofen or Aleve, apply heat to the site, and to follow up if the pain does not resolve.

Other Meds: Famvir (PRN)

Lab Data:

History: History of genital HSV

Prex Illness: No

Prex Vax Illns:

Vaers Id: 393574-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
34.0	F	15-Jun-2010	18-Jun-2010	3	26-Jul-2010	27-Jul-2010	NC		28-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Diarrhoea, Fatigue, Lymphadenopathy, Malaise, Pyrexia

Symptom Text: Severe diarrhea, abdominal pain, fever, stomach pain that lasted 4 weeks, swollen lymph nodes in the groin, malaise and fatigue still ongoing.

Other Meds:

Lab Data: CBC-High WBC with monocytosis noted.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393575-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	08-Aug-2008	Unknown		26-Jul-2010	27-Jul-2010	--	WAES0810USA02499B1	29-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: DIED, ER VISIT, SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature baby

Symptom Text: Information has been received from a consumer concerning her daughter, who on 08-AUG-2008 was vaccinated with the first dose of GARDASIL, 0.5 mL, intramuscular while she was 2 months pregnant. The consumer stated her daughter was almost five and a half to six months pregnant when she started having pains in her side, went to the doctor and was told everything was ok and went home. The next week her pains started again and then felt like contractions, and when she went to the doctor she was already dilated around four or more centimeters and they couldn't stop her contractions. The consumer reported that the baby was born and then died (No further details provided). The mother's experience is reported in WAES 0810USA02499. Upon internal review, preterm labor was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **393580-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		26-Jul-2010	27-Jul-2010	NY	WAES1007USA01625	28-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a physician concerning a patient who "4-5 years ago", in approximately 2005 was vaccinated with the last dose of GARDASIL. The physician stated that the patient was given 3 doses of GARDASIL and then developed multiple sclerosis. The outcome of the patient was not reported. It was unknown if the patient sought medical attention. It was reported that there were a lot of "ambiguity" surrounding this patient. Multiple sclerosis was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **393641-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	M	26-Jul-2010	26-Jul-2010	0	26-Jul-2010	27-Jul-2010	PA		27-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Syncope, Vomiting

Symptom Text: Syncope upon standing approx 5 mins after vaccine. Vomited c/o chills. Fluids, crackers given rested x 1 hour then left feeling better.

Other Meds:

Lab Data: None Hx of syncope 1999 and 2005

History: Hx of syncope 1999 and 2005

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393643-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Jul-2010	13-Jul-2010	0	26-Jul-2010	27-Jul-2010	CA		27-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1656Y	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3042DA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3078AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1378Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Throat tightness

Symptom Text: Gave shots at 3:52 pm. Was told to stat 15 mins. in order to observe her for any reactions. After 15 mins at 4:07 pm she left us know she felt her throat was closing. We let doctor know right away. She immediately injected epinephrine on the patient. She stayed in the office until 8:45 and was continuously observed. Vital signs including O2 sats were monitored, sent home 5:45 pm

Other Meds: None

Lab Data: none

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **393669-1** **Related reports:** 393669-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jul-2010	21-Jul-2010	0	27-Jul-2010	27-Jul-2010	NY		13-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Tremor

Symptom Text: As injection was being given, patient passed out and arms and legs shook.

Other Meds: None

Lab Data:

History: None

Prex Illness: Headache?strep

Prex Vax Illns:

Vaers Id: **393669-2** **Related reports:** 393669-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jul-2010	21-Jul-2010	0	28-Jul-2010	29-Jul-2010	NY	WAES1007USA02542	29-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB427AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 21-JUL-2010 was vaccinated with a first dose of GARDASIL (lot # 659964/1978U), intramuscularly. The patient fainted before the dosage was completed. She got tonic clonic seizure. The patient recovered on the same day. Follow-up information received from a nurse practitioner and licensed practical nurse indicated that the patient had come to the physician's office for her annual physical. On 21-JUL-2010 she was vaccinated with a first dose of GARDASIL (lot # 659964/1978U) and with a dose of HAVRIX (lot # AHAVB427AA). The licensed practical nurse stated that after she had administered the two vaccinations the patient fainted and had seizure that lasted about 20 to 30 seconds. The patient regained consciousness and had recovered. After the incident, the patient waited in the physician's office for one hour and then went home with her mother. The patient did not have a past medical history of seizures and did not have a family history of seizures. Upon internal review tonic clonic seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393679-1** **Related reports:** 393679-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Jul-2010	26-Jul-2010	0	27-Jul-2010	27-Jul-2010	IL		27-Jul-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB417BA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0312Y	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B046DA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3356BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Loss of consciousness, Sensation of heaviness

Symptom Text: Patient states felt dizzy after vaccinations given, patient was reclined and lost consciousness for approx 45 sec, weak and dizzy upon awakening, c/o heaviness feeling in extremities, assessed by EMS personel, f/u of pt been taken by mother to urgent care facility to be assessed.

Other Meds: NONE

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393683-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Jul-2010	22-Jul-2010	0	27-Jul-2010	27-Jul-2010	PA		27-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3431AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061CA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB437BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	03312	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bone pain, Muscle spasms, Pain in extremity

Symptom Text: Received 4 immun today. c/o bilat arm pain and spinal pain. DX: acute bilat deltoid muscle spasm S/P vaccine. TX: Motrin, heat, rest. F/U 2 days with PCP if no improv; return if sx worsen.

Other Meds: Advair 45/21mcg one puff bid;Singulair 5mg hs; albuterol prn

Lab Data: NONE

History: HX OF ASTHMA

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393712-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Jul-2010	27-Jul-2010	0	27-Jul-2010	28-Jul-2010	TX		29-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	13184	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Tonic clonic movements

Symptom Text: Tonic, and Clonic movements without loss of consciousness.

Other Meds: N/A

Lab Data: Patient was referred to Hospital Neurology Department.

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393714-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jul-2010	26-Jul-2010	0	27-Jul-2010	28-Jul-2010	MO		29-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3448AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Pyrexia, Rash

Symptom Text: 7/26/10, PM - Headache, dizziness, Faint rash that quickly faded. 7/27/10, AM - Cont Headache, Rash to Abd, and Low grade Fever 7/27/10 4pm Ibuprofen for fever of 103F 7/27/10 430pm Benadryl for Rash/reaction.

Other Meds: Not currently taking any Meds

Lab Data:

History: Allergic to IV Contrast Dye (CT Scan)

Prex Illness: No

Prex Vax Illns:

Vaers Id: **393716-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Jul-2010	26-Jul-2010	0	27-Jul-2010	28-Jul-2010	CA		29-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0644Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Nausea and Vomiting starting about 30 minutes after Xakia received the vaccine. Lasting episodically through the night.

Other Meds: none

Lab Data:

History: Hx of chronic headaches and R leg pain

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393720-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	M	27-Jul-2010	27-Jul-2010	0	27-Jul-2010	28-Jul-2010	CA		13-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fear, Gait disturbance

Symptom Text: Felt unsteady on feet and felt light headed x a few minutes; NO LOC. Admitted to being afraid.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **393742-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Jul-2010	17-Jul-2010	1	28-Jul-2010	28-Jul-2010	OH		05-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3100AA	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB362BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Injection site erythema, Injection site oedema, Injection site pain

Symptom Text: Patient received an injection of MENACTRA in her (R) deltoid on 7-16-10 here at clinic. Patient went to hosp. ER on 7-17-10 with complaint of pain, redness, and edema at injection site. Patient given scripts for CEPHALEXIN 500 mg one tab bid for 10 days and TRIMETHOPRIM/SULFAMETHOXAZOLE 160/800 mg one tab bid for 10 days for dx of cellulitis. Patient then discharged home.

Other Meds: BENZOYL PEROXIDE

Lab Data: None

History: ACNE

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393745-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	21-May-2010		28-Jul-2010	29-Jul-2010	FR	WAES1007BRa00050	30-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a physician concerning a 20 year old female who has already received two jab of GARDASIL. On approximately 21-MAY-2010 the patient experienced multiple sclerosis. Upon internal review the adverse event multiple sclerosis was considered as an Other Important Medical Event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **393748-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Jul-2010	13-Jul-2010	0	28-Jul-2010	29-Jul-2010	FR	WAES1007USA01738	30-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diarrhoea, Haematemesis, Haematochezia, Nausea, No reaction on previous exposure to drug, Stool analysis, Vomiting

Symptom Text: Information has been received from a pharmacist concerning a 17 year old girl who on 13-JUL-2010 was vaccinated with her second dose of GARDASIL. Concomitant therapy included chloroquine for malaria. Within 1/2 hours after vaccination, the patient began to suffer from severe nausea, vomiting and diarrhea. The patient also had blood in her stools and hematemesis. Because of the severity of the events, the patient went to the hospital (the pharmacist did not know if the patient had been admitted or stayed in the emergency room). Stool testing was done for infectious component (results are pending). The patient had no reactions though following administration of the first dose. It was reported that the patient visited a country a few weeks ago. The pharmacist cannot rule out the possibility of a possible relationship between the events and the vaccine because of the temporal relationship. On 14-JUL-2010, the pharmacist heard back from the patient's mother. The patient had returned home and was feeling better. The patient had improved a little but was still suffering from the afore-mentioned. Additional information has been requested.

Other Meds: chloroquine

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **393749-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		28-Jul-2010	29-Jul-2010	--	WAES1007USA01769	30-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician who was getting ready to give his patient a shot of GARDASIL when the patient informed him a girl friend experienced seizures after getting GARDASIL (lot # not reported). At the time on the report the outcome of seizures was unknown. It was unknown if the patient sought medical attention. Upon internal review seizures was determined to be an other important medical event. Attempts to verify the existence of an identifiable patient have been unsuccessful. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **393751-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jul-2010	08-Jul-2010	7	28-Jul-2010	29-Jul-2010	HI	WAES1007USA02089	30-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0968Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia, Mood altered, Muscular weakness, Sick relative

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with no allergies, birth defects or medical conditions who on 30-APR-2010 was vaccinated IM with a first dose of GARDASIL (lot number: 662299/1099Y). On 01-JUL-2010, the patient was vaccinated IM with a second dose of GARDASIL (lot number: 661758/0968Y) (expiration date: 29-JUN-2012) in the left deltoid. There was no illness at the time of vaccination. On 08-JUL-2010 the patient experienced weakness and bilateral numbness in her lower extremities and upset. The patient was hospitalized from 08-JUL-2010 to 09-JUL-2010 (overnight observation) and discharged from the hospital. The patient left the hospital walking. Multiple, unspecified laboratory tests were performed. On 09-JUL-2010, the patient recovered and she had seen the physician the day after her discharge. The physician stated that the patient's father had a viral infection and she was not sure if the patient's symptoms could have been related to a viral infection exposure. No additional information is expected.

Other Meds: Unknown

Lab Data: computed axial, 07/08/10, head-normal; laboratory test, 07/08/10, CMP=normal; serum alpha-human, 07/08/10, negative; complete blood cell, 07/08/10, 7.3

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **393752-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	31-Jan-2007	25-Apr-2007	84	28-Jul-2010	29-Jul-2010	FR	WAES1007USA02437	09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Migraine with aura, Vaccine positive rechallenge

Symptom Text: Information has been received from a medical consultant for pension office concerning a 18 year female patient who was vaccinated with a second dose of GARDASIL (lot# not reported) on 18-APR-2007. Concomitant medication included hormonal contraceptives (unspecified). Two weeks post vaccination the patient experienced migraine accompanee. Despite ongoing symptoms the patient was vaccinated with a third dose of GARDASIL (lot# not reported) on 17-DEC-2007. Three to four weeks post vaccination the patient developed aggravated migraine accompagnee. Up to the time of reporting unspecified therapy was not successful. At the time of reporting the patient had not recovered. First dose of GARDASIL was given on 31-JAN-2007 and was well tolerated. The reporter assessed the relation to the vaccine as probably. Follow up information has been received from a Health Authority on 16-JUL-2010 (ref. # PEI2010019740). Case was assessed serious from agency, therefore this case was upgraded. Symptoms started about one or two weeks after second dose and reoccurred aggravated 14 and 26 days after third dose, respectively. CT, MRI and cerebrospinal puncture were carried out and showed normal results. The patient had not recovered. Agency coded: migraine accompagnee. The event of migraine accompagnee was considered to be an other important medical event by the Health Authority. Other business partner numbers include E2010-04073. No further information is available.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: computed axial tomography, normal results; magnetic resonance imaging, normal results; spinal tap, cerebrospinal puncture, normal results

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393788-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Jul-2010	22-Jul-2010	0	28-Jul-2010	29-Jul-2010	AZ		17-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pain in extremity, Skin laceration

Symptom Text: Patient feel dizziness, nausea, arm pain 45 minutes after vaccine. Mom took her to ER. next day for a finger cut because of the dizziness.

Other Meds: No

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393794-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	27-Jul-2010	28-Jul-2010	1	29-Jul-2010	29-Jul-2010	TX		30-Jul-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Pain in extremity, Paraesthesia, Pruritus

Symptom Text: Lingering pain in my back and right leg. Constant tingling in my fingers and feet. Itching at the bottom of my feet.

Other Meds:

Lab Data:

History:

Prex Illness: Just arm pain until a few days later...

Prex Vax Illns: Pain and tingling in body~HPV (Gardasil)~1~23.67~Patient

Vaers Id: **393797-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Jul-2010	24-Jul-2010	0	29-Jul-2010	29-Jul-2010	IN		04-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3053AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1332Y	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: After being vaccinated, patient fainted and hit her head on the counter. Pt was able to be aroused and mother was advised to take pt to redimed to check out head. While mother was checking out pt fainted a second time. EMS was contacted and pt was transported to local hospital.

Other Meds: None listed

Lab Data: BP 110/79

History: Asthma as an infant

Prex Illness: None Listed

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Jul-2010	19-Jul-2010	0	29-Jul-2010	29-Jul-2010	PA		17-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3357AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1333Y	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1257Y	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1774Y	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: After receiving 4 vaccines as listed in section 13 pt had syncope.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393809-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Jul-2010	24-Jul-2010	0	29-Jul-2010	29-Jul-2010	RI		04-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	1257Y	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1318Y	2	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bruxism, Dizziness, Dreamy state, Gaze palsy, Hyperhidrosis, Loss of consciousness, Miosis, Moaning, Pallor, Tremor

Symptom Text: After vaccines administered, patient said she felt dizzy. Within seconds patient passed out, eyes rolled in head and teeth clenched on a lollipop she was eating. Patient started to moan, and came to after 15-20 seconds. Color very pale, sweaty, shakey, pupils pinpoint. Upon patient coming around she said she felt like she had a dream. She knew her name and where she was. I elevated her feet and got a cool compress to her head. She drank 10 oz of ginger ale and sat for 20 minutes while her color returned to normal and she said she was feeling much better. Mom said her daughter gets weak at the sight of blood. After 20 minutes 1 had her sit for 10 more minutes with her feet down before being driven home by mom. Patient said she felt almost like herself. I followed-up and called mom's cell phone 90 minutes later and she said patient ate all her lunch and was doing fine. I advised mom to keep a good eye on her and keep activity minimal for the day. Asked to call own DM if symptoms worsened. Vitals: 98/72 right after fainting, 80/56 2 minutes later, 104/68 10 minutes Pulse 76. 108/66 just prior to going home

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393813-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Jul-2010	15-Jul-2010	0	29-Jul-2010	29-Jul-2010	WI		26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3090AA	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3353AA	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1300Y	2	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Client became lightheaded and nauseated 5 minutes after receiving 4 vaccinations. Put head between legs- BP 70/30. Then laid down with legs elevated BP 106/68-Feeling resolved in 5 min. Sat for another 10 min before leaving- no symptoms.

Other Meds: None

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393815-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jul-2010	23-Jul-2010	0	29-Jul-2010	29-Jul-2010	CO		26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1333Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3069AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: Syncopal episode 15 minutes after injection with HPV #1 and MENACTRA. Brief loss of consciousness (less than 1 minute).

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393823-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	20-Jul-2010	20-Jul-2010	0	29-Jul-2010	29-Jul-2010	CA		04-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3061AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1165Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt. given 3 vaccines today, as she got up to leave room she fainted, braced against the wall. Recovered immediately. Denied injury or feeling ill. BP 100/70 (stable). Rested x 20 minutes. Given juice. Recovered.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393829-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Jul-2010	21-Jul-2010	0	29-Jul-2010	29-Jul-2010	UT		05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Loss of consciousness, Nausea, Pallor, Respiratory arrest, Urinary incontinence

Symptom Text: MOC states patient was seated in car and passed out. Eyes rolled back, face pale, not breathing. No shaking/seizure. Episode lasted for 10 seconds. Then patient alert and felt nauseated. No vomiting. Pt urinated self when passed out. MOC reports this happened 5 min's after vaccine. Pt returned to clinic. Pt alert and oriented X 3. VSS. PE WNL.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: vomiting~HPV (Gardasil)~2~13.00~Patient|fainting~HPV (Gardasil)~1~13.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393844-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	22-Jul-2010	22-Jul-2010	0	29-Jul-2010	30-Jul-2010	TX		26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Syncope

Symptom Text: Dizziness, fainting and pallor about <5 mins after vaccination IM. BP 105/58. Pt laid on exam table for about 30 mins and improved. BP 108/58, PR 60, RR 20.

Other Meds:

Lab Data: RBS 95

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393852-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	27-Jul-2010	27-Jul-2010	0	29-Jul-2010	29-Jul-2010	WA		04-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Myalgia, Oropharyngeal pain, Pain, Pain in jaw

Symptom Text: Achy, Myalgia, chills, headache, sore throat, hurt to open jaw.

Other Meds:

Lab Data: Rapid Strep-negative

History: Minocycline

Prex Illness: No

Prex Vax Illns:

Vaers Id: **393869-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Nov-2009	12-Nov-2009	1	29-Jul-2010	30-Jul-2010	FR	WAES1007USA03192	05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1400U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: Case received from a health care professional in a foreign country on 20-JUL-2010 and additional information on 23-JUL-2010. Case medically confirmed. An 18 year old female patient with a medical history of neurodermatitis, had received the first dose of GARDASIL (batch # NH38400, lot # 1400U) in the upper arm on 11-NOV-2009 and one day later she "saw stars", everything went black and she developed dizziness. Since that time dizziness lasted for 6 months and occurred gradually. Neurological and ENT examinations revealed no pathological findings. Laboratory test showed normal results except for iron deficiency. The patient received corrective treatment with unspecified homeopathic medication. Final outcome was unknown. Because of the long duration of symptoms the reaction was considered as serious by the reporter. Dizziness and saw stars, everything went black were considered to be other important medical events. Concomitant medication included hormonal contraceptives (unspecified). The second dose of GARDASIL (batch # NH38400, lot # 1400U) was given on 06-JAN-2010, toleration was not reported. The patient refused the third dose of GARDASIL. The patient was a smoker. The reporter considered the causal relation as unlikely. File closed. Other business partner numbers include E2010-04344.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: neurological examination, no pathological findings; ears, nose, and throat examination, no pathological findings; diagnostic laboratory test, normal, except for iron deficiency

History: Neurodermatitis

Prex Illness: Smoker

Prex Vax Illns:

Vaers Id: **393870-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Mar-2010	23-Apr-2010	31	29-Jul-2010	30-Jul-2010	FR	WAES1007USA03156	09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ29410		Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Angioedema, Circulatory collapse, Condition aggravated, Face oedema, Hypotension, Rash pruritic, Syncope

Symptom Text: Information has been received from an agency via a case line listing via CSL, as part of business agreement, concerning a 12 year old female patient who on 23-MAR-2010 was vaccinated with a 0.5 ml dose of GARDASIL (batch# NK30260, lot# NJ29410) (dose number not reported). On 23-APR-2010, less than 1 month after vaccination, the patient developed rash pruritic, angioedema, circulatory failure and hypotension. It was reported that the patient woke acutely with a hot rash and facial oedema and collapsed getting out of bed. When seen in hospital she was in circulatory collapse with hypotension. It was noted that the patient had a similar episode about 4 months previously (approximately 23-DEC-2009) (predating GARDASIL vaccination by 3 months), for which no cause was found. Immunology clinic review was undertaken, but all tests were negative and the aetiology of these episodes remained unknown. At the time of this report, the patient had recovered from rash pruritic, angioedema, circulatory failure and hypotension. The reporter felt that rash pruritic, angioedema, circulatory failure and hypotension were unlikely related to therapy with GARDASIL. Rash pruritic, angioedema, circulatory failure and hypotension were considered to be immediately life-threatening. A lot check has been initiated. Additional information has been requested.

Other Meds: Unknown

Lab Data: clinical immunology test, ??Jun?10, negative

History: Rash pruritic; Angioedema; Circulatory failure; Hypotension

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393871-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-May-2010	28-May-2010	3	29-Jul-2010	30-Jul-2010	FR	WAES1007USA03148	10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ29430	1	Unknown	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Completed suicide, Death

Symptom Text: Information has been received from the agency via a Case Line Listing via CSL, as part of a business agreement, concerning a 15 year old female patient with a history of depression who on 25-MAY-2010, was vaccinated with the second 0.5 ml IM dose of GARDASIL (batch # NK20450, lot # NJ29430). On 28-MAY-2010, within one week following vaccination, the patient experienced suicide (severe) and died. The cause of death was suicide. The agency felt that suicide was unlikely related to therapy with GARDASIL. No further information is available. A lot check has been initiated. This was originally reported by a practice nurse.

Other Meds: Unknown

Lab Data: Unknown

History: Depression

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393872-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Jul-2010	30-Jul-2010	--	WAES1007USA02539	05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a nurse concerning a friend's daughter who on an unspecified date was vaccinated with a dose of GARDASIL (Lot # not provided). It was reported that the patient on an unspecified date experienced multiple sclerosis. At the time of this report, the patient's outcome was unspecified. The patient sought unspecified medical attention. Upon internal review, the event of multiple sclerosis was considered serious as an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Jul-2010	21-Jul-2010	0	29-Jul-2010	30-Jul-2010	CT		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope

Symptom Text: Pt had a vasovagal syncopal episode approx 10 mins after vaccine administration-pt fell in office and hit the back of her head-recovered quickly in the office but was sent to ER for eval for head trauma on an precautionary measure-uneventful ER visit.

Other Meds: DMPA

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393895-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Jul-2010	27-Jul-2010	0	29-Jul-2010	30-Jul-2010	SD		05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3098AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1497X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Patient complaining of severe left side ache; discribes like a side ache when you run really fast, but worse. Instructed patient to lay down on right side. Do so for about 5 minutes. Related it was getting a little better. Encouraged patient to stay in office for another 5 minutes. No changes in severity or symptoms. Ambulated out of office on her own, with family. 07/29/2010: follow up telephone call made to patient. She states symptom lasted about 45 minutes. No further problems.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393940-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jul-2010	30-Jul-2010	0	30-Jul-2010	30-Jul-2010	MI		05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3068AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B063BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Seizure activity.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393954-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Jul-2010	28-Jul-2010	0	30-Jul-2010	30-Jul-2010	FL		05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	05972	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Allergy to vaccine, Erythema, Eye swelling, Lip swelling, Malaise, Nausea, Swelling face

Symptom Text: C/O not feeling well 30 minutes to an hour after vaccination. Mom says client's face was very bright red and that she was also c/o nausea. No fever, No shortness of breath. The next morning when she got up, mom said client's face looked like she had been in a bad car accident, both eyes were swollen shut, nose was swollen as were her lips. Still, no shortness of breath, so mom contacted her MD and was seen at her MD's office by the ARNP. Dx of allergic reaction to HPV vaccine. Treatment included cold / hot packs to face. Per mom, client got better as the day went on.

Other Meds: None

Lab Data: No tests done. Immunization card & Shots noted as HPV contraindications.

History: None

Prex Illness: None, KNA

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393958-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	Unknown	Unknown		30-Jul-2010	02-Aug-2010	OH		06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3027AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U2936BA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure normal, Fall, Heart rate normal, Syncope

Symptom Text: Immunizations given - client walked to a chair and fainted, fell to the floor. 911 called. EMS, our nurses, safety office evaluated client, BP and pulse were normal. Client woke quickly within 1-2 minutes. Sat up alert and oriented, took nourishment as he had not eaten that day.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **393982-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	28-Jul-2010	28-Jul-2010	0	30-Jul-2010	30-Jul-2010	TX		06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3473AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3352AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	06642	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site pruritus, Injection site swelling

Symptom Text: Swelling, pain, itching at site of immunizations onset approx. 12 hrs after injections. At onset, Dr. advised BENADRYL: by mouth and ice to site. On 7/29/10, advised ZYRTEC and hydrocortisone to site.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **394000-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	M	22-Jul-2010	22-Jul-2010	0	30-Jul-2010	02-Aug-2010	MD		02-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1317Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UFU99BA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Injection site pain, Loss of consciousness, Nausea, Pallor, Vision blurred

Symptom Text: 100PM WITH BLOOD DRAW BECAME DIZZY THEN WENT TO WORK AS A COOK IN HOT SETTING THAT EVENING AROUND 9PM FELT DIZZY, PALE, AND PASSED OUT. HE COMPLAINED OF BLURRED VISION, PALLOR, PAIN AT INJECTION SITE AND NAUSEA FOR 3 DAYS THEN FULLY RECOVERED. HE WENT TO ED ON 7/22/2010 AND THOUGHT HE POSSIBLY HAD A VIRAL ILLNESS.

Other Meds: CLARITIN AS NEEDED

Lab Data:

History: NONE

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394006-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	30-Jul-2010	30-Jul-2010	0	30-Jul-2010	02-Aug-2010	CA		06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1378Y	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF484AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain, Swelling

Symptom Text: Swollen, Pain, Redness on area.

Other Meds: NONE

Lab Data: None

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394024-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Feb-2008	Unknown		02-Aug-2010	02-Aug-2010	CA		06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Vision blurred

Symptom Text: Began with a lightheaded feeling followed by dizziness and clouded vision. Within minutes of getting into the car from the office visit, I fell asleep for the rest of the day.

Other Meds: Ortho Cyclin

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394026-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
2.0	M	Unknown	01-Apr-2007		30-Jul-2010	02-Aug-2010	US	WAES0904USA01551B1	02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthma, Convulsion, Drug exposure during pregnancy, Ear infection, Ear tube insertion, Pyrexia, Speech disorder

Symptom Text: Information has been received from a mother concerning her approximately 2 year old son. In February 2007 and April 2007, the mother with migraine and polycystic ovarian syndrome was vaccinated with the first and second doses of GARDASIL 0.5 mL (lot # not reported), respectively. Concomitant therapy included vitamins (unspecified). Two weeks after receiving dose 2, the mother found that she was two months pregnant. On 13-FEB-2010, the baby was delivered. Subsequently the baby experienced an unexpected fever almost every other day as well as seizures. The baby was also congested all the time and was diagnosed with asthma. At about 6 months old (in approximately August 2007) the baby experienced "a lot of ear infections" and the mother finally switched pediatricians. The pediatricians never referred the baby to an ENT, nor did they suggest tubes in his ears. The baby had tubes placed in his ears about a month or so ago by his new pediatrician, and his speech had really improved a lot- "he was doing much better with that". Now the baby was still having problems with seizures through not as often and his mother thought he was getting much better. The mother felt that seizures, unexplained fever, asthma and "a lot of ear infections" were related to therapy with GARDASIL. Upon internal review, th event of seizures was considered to be an other important medical event. The mother's experiences were captured in WAES# 0904USA01551. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Migraine; Polycystic ovarian syndrome

Prex Vax Illns:

Vaers Id: **394027-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Oct-2007	01-Oct-2007	0	30-Jul-2010	02-Aug-2010	TX	WAES1007USA02866	09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Brain operation, Convulsion, Depression, Epilepsy

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter with no known drug allergies who in October 2007, was vaccinated with a first dose of GARDASIL. There was no concomitant medication. The patient's mother also mentioned how terrible GARDASIL had been in ruining her daughter's life. A few days after receiving the first shot, the patient fell into a deep depression. In January 2008 the patient received a second dose of GARDASIL and at that point the patient fell into an even deeper depression and began having seizures. In June 2008 the patient received a third dose of GARDASIL and apparently at that point she became a full blown epileptic. On an unspecified date the patient was hospitalized (length of stay and hospital demographics not provided); the patient sought unspecified medical attention. It was also reported that the patient has had brain surgery twice. At the time of the report, the patient had not recovered. No laboratory or diagnostic studies were performed. The health professional contacted during telephone follow-up could not supply the following information: dates of vaccination, dose number, lot number, date of event, recovery status, hospital name, and other healthcare provider name and contact information. The health professional stated that the GARDASIL vaccinations were in fact given at their office, but at earlier dates than reported by the consumer. The reporter considered the events "fell into deep depression", "became a full blown epileptic", "how terrible GARDASIL had been in ruining her daughter's life" and "began having seizures" to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394041-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	15-Mar-2010	17-Mar-2010	2	30-Jul-2010	02-Aug-2010	NM		06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Pain

Symptom Text: Cough, body aches. Pt given antibiotics by another primary care physician, inhaler.

Other Meds: Ocella

Lab Data: None

History: Seasonal allergies

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394064-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Jul-2010	Unknown		02-Aug-2010	02-Aug-2010	WI		09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: -Client's mother called to report her daughter is having some increased tenderness at HPV vaccine site 10 days post injection - daughter required IBP & it woke her up - not decrease in pain level.

Other Meds: IBP PRN

Lab Data: Referred client to her own MD if pain continues or worsens, or decrease in mobility, swelling or redness at site.

History: unknown

Prex Illness: None

Prex Vax Illns: Older "felt funny" - never received dose #2~HPV (no brand name)~1~24.00~Sibling

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394077-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	21-Jun-2010	21-Jun-2010	0	02-Aug-2010	03-Aug-2010	MA	WAES1007USA02354	09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Tremor

Symptom Text: Information has been received from a physician concerning a 20 year old female who on 21-JUN-2010 was vaccinated with the first dose of GARDASIL (Lot # unknown). The patient was also vaccinated with a dose of hepatitis A virus vaccine inactivated (manufacturer unknown), in the same office visit. The physician reported that at the day of vaccination, on 21-JUN-2010, the patient experienced seizure-like symptoms (including arm shaking). At the time of reporting, the patient had recovered. The patient did not seek medical attention. Upon internal review, seizure-like symptoms were considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **394078-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	19-Jul-2010	19-Jul-2010	0	02-Aug-2010	03-Aug-2010	CO	WAES1007USA02538	09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0450Z	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Contusion, Dizziness, Fall, Head injury, Laboratory test, Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician and a medical assistant concerning a 23 year old female patient with no medical history and reported as "free of heart murmur" who on 19-JUL-2010, was vaccinated with the first dose of GARDASIL (Lot # 0450Z). There was no concomitant medication. It was reported that after the vaccination, the patient was instructed to wait in the reception area. Then she went back to the exam area and while standing up, "about 10 minutes" after she had received GARDASIL, she felt dizzy, fell back, fainted and hit her head. The physician stated that she was not sure but the patient may have had a seizure. She also stated that she heard the patient fall and when she went to the reception area the patient was unconscious, on the floor sitting up. According to the medical assistant, the patient was unconscious for less than a minute. The patient had bruised her head (specific area not specified). The physician called the patient's name and she regained consciousness immediately and recovered. It was mentioned that the patient had a brief period of amnesia, when she stood up she was coherent. The patient was taken to the treatment room and was given water. The time from the GARDASIL to the time the patient went to the treatment room was about 15 minutes. The patient remained in the physician's office for one hour and a half, before she went home with her mother. She was sent to the emergency room to rule out head injury and had other screenings (unspecified). The patient had an electrocardiogram (EKG) performed which results were abnormal; she was not admitted to the hospital. The patient was referred to a cardiologist. Upon internal review the patient may have had a seizure was considered another important medical event. Additional information has been requested.

Other Meds: None

Lab Data: electrocardiogram, abnormal

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394079-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Aug-2010	03-Aug-2010	TX	WAES1007USA03036	09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Cholecystectomy, Gallbladder disorder

Symptom Text: Information has been received from a nurse concerning a female patient who on an unknown date was vaccinated with a dose of GARDASIL (lot# not reported). Subsequently the patient started experiencing gallbladder problems and had to have her gallbladder removed. She was hospitalized (length and demographics not reported) and underwent surgery. The patient sought unspecified medical attention. At the time of the report, the outcome of the patient was unknown. The reporting nurse considered "experienced gallbladder problems and had to have her gallbladder removed" to be other important medical event due to surgery. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **394080-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Jun-2010	28-Jun-2010	0	02-Aug-2010	03-Aug-2010	FR	WAES1007USA03497	09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion

Symptom Text: Case reported by Health Authority (case n. 120772) through (local case n. IT343/10). Initial report received on 22-JUL-2010. An 11 year old female was vaccinated on 28-JUN-2010 with the first dose of GARDASIL (batch number NL31800, lot number 1353X). On the same day she presented with tonic-clonic convulsions that lasted a few minutes, the patient did not have any pre-existing neurological lesions and was apyretic. She was treated with NOAN. The outcome is recovered on 28-JUN-2010. HA coded tonic-clonic convulsions. The event was reported as not serious by both the reporter and HA upgraded to serious by Company upon internal review. Upon internal review, clonic-tonic convulsions was considered to be an other important medical event. Other business partner numbers included: E2010-04430.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394098-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Apr-2010	28-Apr-2010	0	02-Aug-2010	03-Aug-2010	CO		03-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1434Y	1	Left arm	Subcutaneously	
TDAP	SANOFI PASTEUR	UF500AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	
HEPA	MERCK & CO. INC.	1684Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Muscle contracture, Nausea

Symptom Text: Pt. rec'd GARDASIL in left arm. Immediately following injection pt. passed out while sitting in chair and contracted her arms to chest. Pt. regained consciousness after 10 seconds then became nauseated but had no emesis. Breathing was assessed and pt. rec'd water and peanut butter crackers and rested for ten minutes.

Other Meds:

Lab Data:

History: None known

Prex Illness: Fainting; Nausea

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394122-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	28-Jul-2010	29-Jul-2010	1	02-Aug-2010	03-Aug-2010	GA		04-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	2969BA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0597Z	0	Right arm	Unknown	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB891CA	1	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0089Z	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain in extremity

Symptom Text: Patient reported (L) arm soreness and redness day after vaccination administered denies H/A pain.

Other Meds:

Lab Data:

History: Unknown

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394147-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Aug-2010	03-Aug-2010	0	03-Aug-2010	03-Aug-2010	MA		04-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0565Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Vomiting

Symptom Text: Within 1 minute of receiving vaccine, pt. felt dizzy. Proceeded to vomit. Pt. laid down for 1/2hr. Upon sitting up pt. vomited again.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394150-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	02-Aug-2010	02-Aug-2010	0	03-Aug-2010	03-Aug-2010	AZ		03-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1539Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3078AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB431BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Pallor, Presyncope

Symptom Text: PT BECAME PALE, DIAPHORETIC, AND ALMOST PASSED OUT. B/P WAS 88/40 AND HER PULSE WAS 84. SHE RECOVERED WITHIN ABOUT 20 MIN.

Other Meds:

Lab Data:

History: NONE DISCLOSED BY THE FAMILY

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394152-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Apr-2009	01-Apr-2009	0	03-Aug-2010	04-Aug-2010	--	WAES1007USA03978	10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Fatigue, Headache, Reflexes abnormal

Symptom Text: Information has been received from a lawyer concerning a 14 year old female who in July 2007, April 2009 and January 2010 was vaccinated with the doses of GARDASIL (LOT#s not reported). It was reported that at the time of the report, "now", the patient experienced and in the future will continue to suffer from the neurological effects including seizures, unnatural motor reflexes, headaches, dizziness, fatigue and other symptoms associated with GARDASIL. Upon internal review, a seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **394153-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		03-Aug-2010	04-Aug-2010	FR	WAES1007USA03647	10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Angioedema

Symptom Text: Case received from a physician on 22-JUL-2010. A female patient born in 1988 had received the second dose of GARDASIL (batch # not reported) on an unspecified date. One week later, she experienced Quincke's oedema and was hospitalized. The reporter had no information on the investigations performed, however she specified that the patient was told that "if was related to the vaccine". The patient recovered. She had no relevant personal medical history, no drug allergy, and no concomitant medication. Other business partner numbers included E2010-04411. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394154-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Sep-2009	01-Sep-2009	0	03-Aug-2010	04-Aug-2010	--	WAES1007USA03602	04-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Resuscitation, Tonic clonic movements

Symptom Text: Information has been received from a registered nurse concerning a female teenager, who in approximately September 2009 ("fall 2009") was vaccinated with a dose of 0.5 ml GARDASIL (lot #, injection site and route unspecified). When the patient was given GARDASIL, she had "a seizure with tonic clonic movements" and she "coded". They called 911 and she was revived and recovered "immediately after it happened". Therapy with GARDASIL was discontinued and not reintroduced. The nurse considered the "seizure with tonic clonic movements" to be immediately life-threatening. Reporter also stated that "this event has already been reported to the CDC and VAERS and it has been determined to be unrelated to GARDASIL." No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 394155-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Jun-2010	11-Jun-2010	0	03-Aug-2010	04-Aug-2010	FR	WAES1007USA02584	10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Breath sounds abnormal, Condition aggravated, Gaze palsy, Immediate post-injection reaction, Loss of consciousness, Malaise, Tonic clonic movements

Symptom Text: Information has been received from a Health Authority (HA) (reference numbers PA20100226, PA1000232) concerning a 16 year old female patient with a history of varicella and vagal malaise who received the first dose of GARDASIL (batch number not reported) by intramuscular route on 11-JUN-2010. Ten seconds after injection, the patient felt sensation of malaise with loss of consciousness followed by tonic clonic movements, eye revulsion and noisy breathing. Neither loss urine nor tongue bite were reported. The crisis lasted approximately 30 seconds. The patient was hospitalized on an unspecified date. Blood pressure before crisis was 100/70 and 95/60 after crisis. Sidelying position was placed and the patient remained seated. Then minutes after, when she was still sitting, similar crisis occurred. The patient was taken to the emergency department where electrocardiogram was performed. As results were normal, the patient was discharged that day. On 18-JUN-2010 no crisis occurred again. Further check up i.e cerebral MRI and cardiology consultation pending. The HA had coded the events: "loss of consciousness" and "tonic clonic movements". The HA assessed the causal relationship between the reported reactions and vaccination as "possible" (C2S2I2) according to the method of assessment. Other business partner numbers include: E2010-04392. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure measurement, 11Jun10, 100/70, before crisis; blood pressure measurement, 11Jun10, 95/60, after crisis; electrocardiogram, normal

History: Varicella; Malaise

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394161-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Jun-2009	30-Jun-2009	1	03-Aug-2010	04-Aug-2010	FR	WAES1001USA03318	10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1050U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal pain, Pain, Pain in extremity

Symptom Text: Case received from a health care professional on 08-JAN-2010. It was reported by a gynecologist that a 16 year old female patient received a complete series of three doses of GARDASIL (D1: lot # 1050U, batch # NH32140; D2 lot # 1695U, batch # NH25730; D3: lot # 1285U, batch # NH35150) intramuscular, into the left upper arm on 29-JUN-2009, 03-SEP-2009 and on 04-JAN-2010. Since 30-JUN-2009 the patient complained of intermittent pain in left arm especially while moving it. Despite ongoing symptoms she was vaccinated with D2 and D3 of GARDASIL. For some time (not otherwise specific) the patient also developed pain in right hand. The medical familial history included rheumatoid arthritis by the patient's mother and grandmother. Follow up information has been received. The case was initially reported as non serious and was upgraded to serious upon internal review (due to other important medical event). The reporter was contacted by phone. Several unspecified examinations revealed diagnosis of rheumatism. At the time of reporting the patient showed no symptoms. The case is closed. Other business partner numbers include E2010-00111. No further information is available.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, several unspecified examinations revealed diagnosis of rheumatism

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394164-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		03-Aug-2010	04-Aug-2010	FR	WAES1007USA03498	10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Multiple sclerosis, Paraesthesia, Vaccine positive rechallenge

Symptom Text: Information has been received from a gynecologist concerning an "adult" female patient who had already developed tingling and weakness after the first and second doses of GARDASIL (vaccination dates not provided). On an unspecified date, the patient was vaccinated with the third dose of GARDASIL (Lot #, route and site not reported). According to the patient she developed tingling and weakness "after the injections". Over the course of time the patient was diagnosed with multiple sclerosis. The patient contacted the reporting physician as she had found references in the internet which indicated that the frequency of multiple sclerosis (MS) was increasing after vaccination with GARDASIL. Other business partner numbers include E2010-04450. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Tingling; Weakness

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394170-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Jul-2010	28-Jul-2010	0	03-Aug-2010	03-Aug-2010	NY		10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B042BA		Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	02452	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	05652	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	43465AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Posture abnormal

Symptom Text: Pt. felt dizzy and nauseous and slumped down on the floor.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394179-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	M	25-Jun-2010	Unknown		03-Aug-2010	03-Aug-2010	PR	PR1021	10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1539Y		Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3557AA		Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	02262	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscle rigidity, Syncope

Symptom Text: AFTER RECEIVING THE VACCINES THE PATIENT FAINTED AND BECAME RIGID. AFTER A FEW SECOND HE RESPONDED. WAS TAKEN TO THE ER.

Other Meds:

Lab Data: BP 92/51 PULSE 62

History: ASTHMA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394190-1** **Related reports:** 394190-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	M	03-Aug-2010	03-Aug-2010	0	03-Aug-2010	04-Aug-2010	IL		04-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: syncope 4:05 PM

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **394190-2** **Related reports:** 394190-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	M	03-Aug-2010	03-Aug-2010	0	09-Aug-2010	11-Aug-2010	IL		16-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3359AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0565Z		Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion, Dizziness, Face injury, Headache, Immediate post-injection reaction, Lethargy, Syncope

Symptom Text: Patient received MENACTRA, DTAP and HPV vaccinations. He fainted promptly afterwards and struck his (L) frontal orbital area of face, causing bruising, regained consciousness within 2 minutes after fainting, but continued headache and lethargy and felt faint again when sitting up. Paramedics were called for transport to E.R.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394191-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Aug-2010	02-Aug-2010	0	03-Aug-2010	04-Aug-2010	CA		04-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1539Y	0	Gluteous maxima	Intramuscular	
	TDAP	SANOFI PASTEUR	U3042CA	0	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disturbance in attention, Dizziness

Symptom Text: Dizziness, light-headedness, impaired concentration.

Other Meds: Lexapro

Lab Data: None

History: Scoliosis, Panic Disorder, Obesity

Prex Illness: lower back pain

Prex Vax Illns:

Vaers Id: **394219-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Feb-2010	21-Feb-2010	18	04-Aug-2010	05-Aug-2010	TX		03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0969Y	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Confusional state, Convulsion, Dizziness, Fall, Grand mal convulsion, Headache, Musculoskeletal stiffness, Postictal state, Somnolence, Staring

Symptom Text: On 2/21/10, pt suffered a severe seizure and was transported by ambulance to the hospital where she was hospitalized for two nights and underwent many tests. The following information was obtained through follow-up and/or provided by the government. 08/16/10. PCP visit for DOS 2/21/10. Pt c/o dizziness, falling down, tonic-clonic seizure, confused. Pt taken to ER and had another episode of seizure. 08/16/10. H&P and DC summary for DOS 02/21/10-02/23/10. DC DX: seizure. Pt admitted for generalized tonic-clonic seizure. Pt had 2 sz episodes. Pt had neck extension, starring spell then flexure of extremities. Pt postictal, confused and sleepy after seizure. Attending MD thought this was of unclear etiology. Neuro exam normal, but Pt c/o HA. Tx: Ativan, Dilantin, IVF. Pt discharged home in stable condition and provided with sz precautions.

Other Meds:

Lab Data: CAT Scan, EEG, and MRI The following information was obtained through follow-up and/or provided by the government. Labs and DX studies: brain MRI negative, EEG essentially normal to borderline EEG.

History: The following information was obtained through follow-up and/or provided by the government. PMH: recent URI, h/o febrile seizure at 1 y.o., tonsillectomy, ADHD, poor school performance, needed oxygen after birth. Allergies: none.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **394225-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		03-Aug-2010	05-Aug-2010	NJ		13-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3340AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C33838A	0	Left arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	B880AA	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Hypotension, Loss of consciousness, Pulse abnormal

Symptom Text: Approximately 10 minutes after the administration of vaccines, the patient became diaphoretic and lost consciousness. Blood pressure was low and pulse thready within 15 minutes VS and sense of feeling well was normal.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394228-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Dec-2009	08-Dec-2009	1	04-Aug-2010	04-Aug-2010	WI		10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0086X	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3355AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3058AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Injection site erythema, Injection site swelling, Injection site warmth, Rash

Symptom Text: Swelling about size of softball, redness, warmth at site (LD); "slight" temp elevation; rash over chest. Immun about 1300, reaction < 24 hr > 12 hr. Resolved within couple days. Ibuprofen only med given.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394270-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jul-2010	31-Jul-2010	1	04-Aug-2010	05-Aug-2010	VA		06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0569Z	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1377Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Fatigue, Headache, Vision blurred

Symptom Text: Blurred vision, headache, stomach ache and fatigue 24 hours after receiving vaccine -> GARDASIL #2.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394273-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Aug-2010	04-Aug-2010	0	04-Aug-2010	05-Aug-2010	KY		05-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0331Z	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3473AA	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB437AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Anxiety, Disorientation, Dizziness, Fall, Hyperhidrosis, Immediate post-injection reaction, Loss of consciousness, Nausea, Pallor, Tachycardia

Symptom Text: Administered HEP A & MCV in pts. right arm & then proceeded with HPV in left arm. Immediately after withdrawing the needle, pt. stated she felt dizzy & passed out. Patient's mom and I were in the room and patient, who was seated on the exam table, fell back against the wall. Her mom and I lowered her into a lying position and Dr. came into the room. Patient regained consciousness in less than 30 seconds but was disoriented and said she did not remember anything after saying she felt dizzy. Patient continued to lie down with mom in the room. A wet washcloth was applied to patient's forehead. Patient was pale, diaphoretic, and tachycardic. She was later complaining of nausea. She did not vomit. After approximately 25 minutes, patient sat up on the exam table. She was apprehensive that she would faint again. Patient was able to walk out of the clinic approximately 40 minutes after the fainting episode.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394292-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Aug-2010	02-Aug-2010	0	04-Aug-2010	05-Aug-2010	NJ		06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Approximately 2 hours following receipt of GARDASIL #2, patient developed hives all over body-face, no shortness of breath. Mother denied other new exposures. Resolved with BENDARYL. Lesser hives recurred subsequent 2 days.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394298-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	04-Aug-2010	04-Aug-2010	0	04-Aug-2010	05-Aug-2010	PA		05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0981Y	1	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB285AB	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Drug exposure during pregnancy, Pallor, Unresponsive to stimuli

Symptom Text: Patient complainted of feeling dizzy and light-headed. Staff responded by offfering snacks. Soon after, Patient became pale and unresponsive for 60 seconds. Awoke spontaneously and offered juice.

Other Meds:

Lab Data: Urine pregnancy test was positive

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394299-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Jul-2010	29-Jul-2010	0	04-Aug-2010	05-Aug-2010	--		10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1539Y	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3049CA	3	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Swelling at the site, redness, heat at the site, painful to the touch.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **394302-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	02-Aug-2010	02-Aug-2010	0	04-Aug-2010	05-Aug-2010	WI		05-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised, Urticaria

Symptom Text: A couple of hours after receiving HPV vaccine, patient developed hives and was itching all over her body. Denied any new products being used or eating any new foods or taking any other medication.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394322-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	03-Aug-2010	03-Aug-2010	0	05-Aug-2010	05-Aug-2010	AZ		13-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB431BA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3078AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0338Z	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Pallor

Symptom Text: PT STATED HE WAS GOING TO FAINT, TURNED PALE AND PASSES OUT. HIS VS WERE AS FOLLOWS: B/P 92/50 PULSE 88 RESP 14. USED AMMONIA AMPULE TO RISE HIM, LAID HIM ON THE FLOOR, ICE PACK TO BACK OF NECK. PT. RECOVERED WITHIN 15 MINUTES.

Other Meds:

Lab Data:

History: NONE MENTINED BY FAMILY DURING ASSESSMENT

Prex Illness: NONE MENTIONED BY FAMILY DURING ASSESSMENT

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394337-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	04-Aug-2010	04-Aug-2010	0	05-Aug-2010	05-Aug-2010	RI		06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	
	PPV	MERCK & CO. INC.	0449Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope approx 15 seconds. VS repeated in 10 min intervals BP stabilized at 122/68 HR 86 RR 20, oral fluids given to pt.

Other Meds:

Lab Data:

History: Allergies= orange oil; peanut; penicillin; vanilla tincture

Prex Illness:

Prex Vax Illns:

Vaers Id: **394339-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jul-2010	29-Jul-2010	0	05-Aug-2010	05-Aug-2010	AZ		06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0337Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope, Tonic clonic movements

Symptom Text: Immediate syncopal event. Supine x 10 min. 2nd syncopal event after sitting up x approximately 5 min. This time w/some tonic-clonic jerks.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **394354-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-Dec-2007	01-Jan-2008	11	05-Aug-2010	06-Aug-2010	FR	WAES1007USA03865	06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1401F	0	Left arm	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Alopecia, Androgenetic alopecia, Asthenia, Blood pressure systolic decreased, Bronchitis, Chronic sinusitis, Condition aggravated, Dizziness, Fatigue, Headache, Heart rate increased, Infection susceptibility increased, Laryngitis, Loss of consciousness, Menstruation irregular, Migraine, Muscular weakness, Nasopharyngitis, Nausea, Orthostatic intolerance, Pain, Pallor, Performance status decreased, Photosensitivity reaction, Sinusitis, Syncope, Thirst, Tonsillitis, Vertigo, Weight fluctuation

Symptom Text: Information has been received from a Health Authority (reference # PEI2010019668). Case medically confirmed. To be noted that the medical letters/hospital reports contain ambiguous, not always congruent information, particularly concerning the beginning of migraine symptoms. A 13 year old female with a medical history of menstrual bleeding in 2006 and administration of hormonal contraception (unspecified) for one year had received the first dose of GARDASIL (lot # 1401F, batch NG00010) in the left upper arm on 21-DEC-2007 and with a second dose of GARDASIL (lot # 1114U, batch NH10940) in the left upper arm on 14-AUG-2008. Since beginning of 2008 she developed relapsing syncopes and a decreased performance status and since July 2008 frequent infections (laryngitis, bronchitis, tonsillitis, and common colds). After the second vaccination physical and mental performance furthermore aggravated. In September 2008, she presented to a dermatologist with hair loss. On 11-SEP-2008, alopecia androgenetica was diagnosed. On 19-NOV-2008, the patient presented to an outpatient department for pediatric psychosomatics. An integrated therapy recommended. Since January 2009, the patient presented to a general practitioner who prescribed homeopathic medication due to dizziness, syncopes, fluctuation of weights, regularly occurring pain, chronic fatigue, photosensitivity and headache. Cytomegalovirus and hepatitis A, B and C were excluded. From 12-FEB-2009 to 18-FEB-2009, the girl was hospitalized. Family history revealed depression and epilepsy of the patient's father. According to the mother the patient generally eats few. At that time the patient had a weight of 58.6 kg and a height of 163 cm. By clinical investigation of the symptoms (with an increased thirst in addition), including EEG (electroencephalogram), ECG (electrocardiogram) and abdominal sonography, following diagnoses were excluded: diabetes insipidus, hypothyroidism, epilepsy, ocular diseases, heart diseases. Endocrinal diagnostics (thyroid values and cortisol) show

Other Meds: Unknown

Lab Data: electroencephalography, 12Feb09, excluded: diabetes insipidus, hypothyroidism, epilepsy, ocular diseases; electrocardiogram, 12Feb09, excluded: heart diseases; magnetic resonance imaging, 25Mar09, normal results of neurocranium, showed in a

History: Bleeding menstrual heavy; Contraception

Prex Illness: Vertigo; Headache unilateral; Nausea; Vomiting; Photosensitivity; Ear disorder; Excessive eye blinking

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394362-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2009	12-Aug-2009	0	05-Aug-2010	06-Aug-2010	PA	WAES1001USA03408	09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alpha 1 foetoprotein, Amniocentesis, Amniotic fluid volume decreased, Anaemia, Caesarean section, Cardiac stress test, Drug exposure during pregnancy, Foetal distress syndrome, Laboratory test, Ultrasound scan

Symptom Text: Information has been received from a certified medical assistant, for GARDASIL, a Pregnancy Registry product, concerning a 17 year old female with no pertinent medical history reported and no known drug allergies who on November 2008, August 2009 and 11-DEC-2009 was vaccinated intramuscularly with the first 0.5 mL, second 0.5 mL and third 0.5 mL dose of GARDASIL (LOT# first dose 659180/1758U, second dose 659964/1978U and third dose 663453/0249Y), respectively. There was no concomitant medication. The patient was found to be pregnant since the pregnancy urine test was positive. No adverse effect was reported. The date of the last menstrual period was in October 2009, the estimated date of delivery is in July 2010. Follow-up information was received which reported that the female with no previous pregnancies or births and was pregnant, and the estimated conception date was possibly 09-NOV-2009. The date of the last menstrual period was in October 2009, the estimated date of delivery is 08-AUG-2010. The Maternal serum-alpha-fetoprotein (MSAFP) and amniocentesis was performed by obstetrician/Gynecologist (OB/GYN) and no results were reported. Follow-up information was received which provided specified dates of the first dose and second dose. It was noted the first dose of GARDASIL was received on 14-NOV-2008 and the second dose on 12-AUG-2009. Follow-up information was received which reported that the female during entire pregnancy time period was taking prenatal vitamins, daily for prenatal care and SLOW FE, daily for anemia. During pregnancy/delivering, the patient had complication of low amniotic fluid and fetal distress (had captured in NWAES # 1001USA03408B1). Obstetric labs, ultrasound and fetal stress test were performed and outcomes were unknown. On 20-JUL-2010, at LMP of 38 weeks the patient through C-section delivered a normal male infant, weight "5 pounds 1.6 ounce" and length 19.5 inches. Upon internal review, C-section was considered to be an other important medical event. The infant's experience had cap

Other Meds: SLOW FE; vitamins (unspecified)

Lab Data: Beta-human chorionic, positive for urine test

History:

Prex Illness: Pregnancy NOS (LMP = 10/1/2009); Anaemia

Prex Vax Illns:

Vaers Id: **394363-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	23-Mar-2010	24-Mar-2010	1	05-Aug-2010	06-Aug-2010	CA	WAES1006USA04303	06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0821Y	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Eye irritation, Eye pruritus, Pruritus, Rash erythematous

Symptom Text: Information has been received from a physician concerning a female patient with yeast allergy who on an unspecified date was vaccinated with a first dose of GARDASIL (Lot# unknown). The physician reported that the patient experienced itching after receiving GARDASIL. The patient sought unspecified medical attention. At the time of the report, the patient had recovered from itching (date unknown). Therapy with GARDASIL was discontinued. Follow up information has been received from a physician concerning a 22 year old female patient with yeast allergy who on 23-MAR-2010 was vaccinated with a first dose of GARDASIL (Lot # 662765/0821Y, expiry date 25-JUN-2011), IM in the left deltoid. On 24-MAR-2010 at 2:00 am the patient experienced rash (red itchy), shortness of breath, lightheadedness, dizziness, and itchy/burning eyes. The physician stated that on 30-MAR-2010 the patient recovered. The patient sought medical attention. The reporting physician considered rash (red itchy), shortness of breath, lightheadedness, dizziness, and itchy/burning eyes to be other important medical events. Additional information is not expected.

Other Meds: Unknown

Lab Data: serum immunoglobulin G, yeast allergy

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vaers Id: **394364-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Nov-2009	Unknown		05-Aug-2010	06-Aug-2010	FR	WAES1007USA03179	06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ02680	1	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Abnormal behaviour, Aggression, Amenorrhoea, Antisocial behaviour, Apathy, Back pain, Decreased activity, Depression, Disturbance in attention, Dysphagia, Eating disorder, Educational problem, Fatigue, Headache, Hypersomnia, Influenza like illness, Lethargy, Malaise, Medical diet, Mood swings, Muscular weakness, Nausea, Neuropathy peripheral, Oedema peripheral, Pain in extremity, Paraesthesia, Pyrexia, Sensation of heaviness, Tremor, Vomiting

Symptom Text: Information has been received from the agency via a Case Line Listing via CSL, as part of a business agreement, concerning 16 year old patient who in September 2009 was vaccinated with a first IM dose of GARDASIL (lot # not reported). Since receiving the first dose of GARDASIL the patient had been unwell, she had a sore arm, slept a lot, headaches, flu-like symptoms, severe mood swings, was antisocial and became amenorrhoeic. On 13-Nov-2009 the patient was vaccinated IM with a second 0.5 ml dose of GARDASIL (lot# NJ02680, batch# NJ46520). A week following vaccination with the second dose of GARDASIL, the patient's arm became "dead" heavy and very weak, with paresthesia. over the months the parent's diary reported that her daughter had continuing extreme, headaches, concentration problems, back and abdominal pain, swollen fingers and shaking left hand. She also became aggressive and difficult to deal with. School performance declined and behavior in general became out of character. The patient had been a keen sportswoman and had lost all motivation to participate. In the patient's diary were documented fluctuations in spectrum of symptoms which largely referred to behavior, motivational issues as well as headache, back pain and arm paraesthesias, but had also included new symptoms such extreme fatigue, fevers, depression, nausea, vomiting and difficulty eating and swallowing certain types of food. The diary documented the events until 20-MAY-2010. It was reported that "other factors" included "nutritional supplements". In January 2010 the patient was placed on therapy with citalopram (PO) and metoclopramide (PO), for an unknown indication. At the time of the report, the patient had not recovered. The agency did not classify the relationship between neuropathy, headache, concentration impaired, behaviour abnormal and lethargy to vaccination with GARDASIL. The agency considered the events of neuropathy, headache, concentration impaired, behaviour abnormal and lethargy to be disabling. This was originally reported by

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394365-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		05-Aug-2010	06-Aug-2010	--	WAES1007USA03987	06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse at the physician's office concerning a 14 year old female patient who on an unknown date was vaccinated with the first dose of GARDASIL (lot # and route not reported). On an unspecified date the patient received the second dose of 0.5 ml GARDASIL intramuscularly (lot # not reported). Concomitant therapy was not reported. After getting the second dose of vaccine the patient experienced seizure like reaction. The nurse also reported that the patient had a similar reaction after the first dose as well. The patient had sought medical attention and had recovered from the seizure like reaction "after stopping therapy". Upon internal review, seizure like reaction is considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **394366-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Jul-2010	02-Jul-2010	0	05-Aug-2010	06-Aug-2010	FR	WAES1007USA04101	06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Case received from the Health Authority on 28-JUL-2010 under the reference case number ES-AGEMED-722539241. Case medically confirmed. A 15 year old female patient, 35 kilograms with a medical history of fainting-fits had received an injection of GARDASIL (batch number not reported) via intramuscular on 02-JUL-2010 on the same day, latency the patient experienced a loss of consciousness. Examination performed on 02-JUL-2010, showed an arterial pressure of 121/67 mmHg. The patient recovered on the same day, on 02-JUL-2010, within a few seconds. In the HA's report only faint was coded. Case reported serious by health authority with other medically important condition as criteria. Case is closed. Relevant Test/Laboratory data: Diastolic BP: 67 mmHg. Systolic BP: 121 mmHg. Other business partner numbers included E2010-04525. No further information expected.

Other Meds: Unknown

Lab Data: blood pressure measurement, 02Jun10, 121 mmHg, Diastolic: 67 mmHg; Systolic: 121 mmHg

History: Syncope

Prex Illness:

Prex Vax Illns:

Vaers Id: **394371-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	27-Jul-2010	03-Aug-2010	7	05-Aug-2010	06-Aug-2010	GA		06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0565Z	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Joint swelling, Oropharyngeal pain, Pruritus, Rash generalised, Urticaria

Symptom Text: Generalised rash / urticaria/ pruritis / swollen joints , throat pain

Other Meds:

Lab Data: None

History: NO

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394382-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Aug-2010	04-Aug-2010	0	05-Aug-2010	06-Aug-2010	WI		06-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3353AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1436Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0216Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain in extremity

Symptom Text: right arm became very sore and red

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394384-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Aug-2010	04-Aug-2010	0	05-Aug-2010	09-Aug-2010	MD		09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3488BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0096Z	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB437AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3338AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Hypotonia, Peripheral coldness

Symptom Text: Patient became flaccid, cool to touch, and seizer activity for 3-4 seconds.

Other Meds:

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394387-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Aug-2010	05-Aug-2010	0	05-Aug-2010	09-Aug-2010	OR	LOT0075Y	09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0075Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ear discomfort, Feeling abnormal, Pallor, Vision blurred

Symptom Text: PT. COMPLAINED OF BLURRINESS TO HER VISION AND HEARING "BLOCKAGE". SKIN TURNED PALE AND PT STATED SHE DIDN'T FEEL OK. COLD WATER GIVEN AS WELL AS COLD WASH CLOTH. PT REFUSED TO LIE DOWN AND REMAINED IN AN UPRIGHT POSITION. PT WAS OBSERVED FOR 30 MINUTES. AFTER STATING SHE FELT ALOT BETTER PT. WAS D/C'D TO HOME.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: PT. C/O VISION BLURRINESS AND "HEARING BLOCKAGE" FOR APPROXIMATELY 2-3 MINUTES. C/O NOT FEELING "OK". PALENESS TO SKIN WAS ALSO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394420-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Jul-2010	27-Jul-2010	1	06-Aug-2010	09-Aug-2010	IN		10-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1302Y	1	Left arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB379BA	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1333Y	3	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discharge, Injection site erythema, Injection site pain, Injection site swelling, Injection site vesicles, Injection site warmth

Symptom Text: Patient c/o injection site being very swollen, red, painful, and hot to the touch. Patient presented on 7-28-10 with above symptoms. Upon exam, patients (L) arm has blisters around injection area. Also had clear yellow drainage from both injection sites on (L) arm. Patient was given KEFLEX, Prednisone, Hydrocortisone cream.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **394428-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Dec-2009	29-Dec-2009	0	06-Aug-2010	09-Aug-2010	IN		09-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Cyanosis, Dysstasia, Nervousness, Palpitations, Paraesthesia, Pyrexia, Syncope

Symptom Text: Daughter collapsed and could not get up by herself. Low grade fever, shaky, seizure type symptoms. Complains of racing heart, blue hands, tingling hands and feet.

Other Meds:

Lab Data: Blood work; EKG

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394429-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Aug-2010	04-Aug-2010	0	06-Aug-2010	09-Aug-2010	FL		02-Sep-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	U3035CA	5	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0222Z	1	Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U3354BA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1332Y	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB431BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Fatigue, Injection site pain, Muscle rigidity

Symptom Text: Approximately five minutes after receiving vaccinations patient, who was sitting in a chair, became rigid *for approximately equal to three seconds (*rigid limbs with some jerking present). Patient aroused; was oriented to person, place, time. States did not eat breakfast today. Mom states patient was "nervous" about vaccinations. Vital signs monitored. Had pt rest on exam table. Pt. was given Sprite to drink/crackers to eat. Left clinic without difficulty at 10:05 AM - pt states feels "tired". Requested mom call this RN to inform of pt. status later today. Approximately equal to 4:30 PM - 8/4/10 - phone call to mom. Mom states pt. "doing fine" / "she's fine" but has some injection site soreness. 8/5/10 2:10P Phone call to parent of client - left voice msg. Re: follow up post injections. Requested call back from parent. 8/5/10 3:05P Return call from parent - States "she is fine and she is acting just like normal".

Other Meds: Folic acid; "iron pill"

Lab Data:

History: Sickle cell trait per parent

Prex Illness: None

Prex Vax Illns:

Vaers Id: **394439-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Apr-2010	31-May-2010	53	06-Aug-2010	09-Aug-2010	FR	WAES1007USA03418	26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ49350	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Colitis ulcerative, Condition aggravated, Diarrhoea haemorrhagic, Large intestinal ulcer

Symptom Text: Information has been received from a consumer under the reference number RA-104-2010 on 16-JUL-2010 and transmitted by agency. A 13-year-old female patient had received the first dose of GARDASIL (LOT # NJ49350, batch # NL30780) on 08-APR-2010 and the second dose (batch #, site of administration and route not reported) on 27-MAY-2010. Two days after the administration of the first dose, the patient experienced diarrhoea with blood and she had visited the emergency room. She was treated with SALOFALK 250 and a colonoscopy with biopsy was done to search for ulcerative colitis. The colonoscopy showed several ulcers but the results from the biopsy were not conclusive. Four days after the administration of the second dose, the patient experienced again diarrhoea with blood but for a shorter period of time. The patient has been followed in the gastroenterology medical visit and a visit to the doctor was planned on 20-JUL-2010. The patient's medical history was not reported and previous reaction to other drugs was unknown. The outcome was recovered. Follow-up information received on 27-JUL-2010: Case medically confirmed (on 27-JUL-2010). The gastroenterologist reported that the results of the second colonoscopy and biopsy confirmed a diagnosis of ulcerative colitis and the patient was still medicated with mesalamine. According to the gastroenterologist, the event was not related with the administration of the vaccine. The patient had recovered and will be followed in the pediatrics medical visit. For the moment, no more information was provided regarding the administration of the third dose. Upon internal review ulcerative colitis was considered medically significant. Other business partner numbers included: E2010-04460. No further information is available.

Other Meds: Unknown

Lab Data: Colonoscopy, ??Apr10, several ulcers; biopsy, ??Apr10, to search for ulcerative colitis were not conclusive; colonoscopy, second colonoscopy confirmed a diagnosis of ulcerative colitis; biopsy, second biopsy confirmed a diagnosis of ulcerat

History: Bloody diarrhoea; Gastrointestinal ulcer

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394441-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Jun-2010	27-Jun-2010	2	06-Aug-2010	09-Aug-2010	FR	WAES1008USA00066	20-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Hypoaesthesia, Injection site pain, Muscular weakness, Paraesthesia, Photophobia, Polyneuropathy, Sensation of heaviness, Sensory disturbance, Vomiting, Weight decreased

Symptom Text: Case received from a pharmacist on 28-JUL-2010. Case medically confirmed. An 18 year old female patient had received the first dose of GARDASIL (Batch # not reported) in the arm on 25-JUN-2010. On 27-JUN-2010 ie 2 days later, she experienced pain at the site of injection, with heaviness and numbness of the vaccinated arm. She also experienced tingling in the fingers and the toes. 4 days after vaccination, the patient experienced vomiting for 4 days, resulting in a weight loss of 3 kg. Fatigue, muscular weakness in the legs then in the arms, sensation of absence and eye discomfort to light were also reported with no specified date of onset. Electromyogram was performed and polyradiculoneuritis was diagnosed. The pharmacist suggested possible diagnosis of Guillain Barre Syndrome. The patient started corrective treatment with prednisone on 28-JUL-2010 to be discontinued on 02-AUG-2010. Brain MRI was to be performed in mid August 2010 due to sensation of absence and discomfort to light. The reporting pharmacist considered the adverse events to be other important medical events. Other business partner numbers included E2010-04529. No further information is available.

Other Meds: Unknown

Lab Data: electromyography, polyradiculoneuritis

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394468-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Aug-2010	06-Aug-2010	1	06-Aug-2010	09-Aug-2010	CO		10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local reaction, Rash

Symptom Text: Skin rash, localized to arms. ? if related to vaccine.

Other Meds:

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **394501-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Aug-2010	06-Aug-2010	0	09-Aug-2010	09-Aug-2010	MI		20-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Immediate post-injection reaction, Tonic clonic movements, Urinary incontinence, Vomiting

Symptom Text: Immediately post vaccine pt slumped to floor, had tonic clonic movement of arms and legs and was incontinent of urine - After 10 minutes she had improved somewhat but upon trying to ambulate she vomited x 2. She was then transported to the ER by ambulance.

Other Meds:

Lab Data:

History: ADD; Pt on CONCERTA 54mg Q day.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394518-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	04-Aug-2010	04-Aug-2010	0	06-Aug-2010	09-Aug-2010	MD		10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3336AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0597Z	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061BA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site warmth

Symptom Text: Large, flat erythematous, warm, pruritic patch B/L arms following vaccine administration. (L) arm lesion 4cm diameter. (R) arm lesion 2.5cm. Advised BENADRYL and heat.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **394621-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	01-Jul-2010		09-Aug-2010	10-Aug-2010	TN	WAES1007USA03598	23-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection, Precancerous cells present

Symptom Text: Information has been received from a physician concerning a 22 year old female with allergic reaction to CECLOR, tetracycline, penicillin and sulfa who on 09-AUG-2007 was vaccinated with the first dose of GARDASIL (0.5ml, IM), the second dose (0.5ml, IM) was on 06-DEC-2007 and the date of third dose (0.5ml, IM) was unknown. Concomitant therapy included unspecified "birth control" medication. In July 2010 PAP results indicated the patient had high risk HPV. The patient had a colposcopy and biopsy and the results that showed high dysplasia and severe dysplasia. The patient's results showed "precancerous". the patient had routine office visit and would have surgery in the office. The patient had not recovered at time of report. High risk HPV and precancerous dysplasia were considered to be other important medical event. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: colposcopy, 07/??/10, high dysplasia and severe dysplasia; biopsy, 07/??/10, high dysplasia and severe dysplasia; Pap test, 07/??/10, high risk HPV

History:

Prex Illness: Allergic reaction to antibiotics; Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394622-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	23-Jul-2010		09-Aug-2010	10-Aug-2010	OH	WAES1007USA03810	23-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Information has been received from a nurse concerning an 18 year old female patient who on an unspecified date was vaccinated in the arm with a second dose of GARDASIL (lot number not provided). The nurse reported that on 23-JUL-2010 the patient passed out and suffered a chronic seizure. On an unspecified date the patient recovered. The patient sought unspecified medical attention. The reporting physician considered the chronic seizure to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394637-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	30-Jul-2010	30-Jul-2010	0	09-Aug-2010	10-Aug-2010	GA		10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0664Z	0	Left arm	Intramuscular	MNQ

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Pallor, Tremor

Symptom Text: 1400 - HPV (GARDASIL administered), 1415 Pt reported shaking and sweating, tremors noted, skin pale, sweating noted. EMS called by RN. Pt. remains alert and oriented. 1440 Pt transported to Medical Center via ambulance.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394663-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	05-Aug-2010	05-Aug-2010	0	09-Aug-2010	10-Aug-2010	AZ		12-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU(H1N1)	SANOFI PASTEUR	UP019AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unresponsive to stimuli

Symptom Text: Client received HPV and H1N1 about 1:30p.m. He was sitting up in a chair as per protocol after shots and was observed with his head down, not responding to verbal commands. He was assisted to the floor. VS WNL. He responded to command to squeeze hand, but could not open eyes or raise hand. O2 2L/NC applied. ? and arrived at 1:42p.m. Client then opened his eyes and became responsive. He left with his mother - no hospitalization.

Other Meds:

Lab Data:

History: Seizures- but never with immunization

Prex Illness: History of seizures-none in 2yrs

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394679-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Aug-2010	06-Aug-2010	0	09-Aug-2010	10-Aug-2010	WA		10-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disorientation, Fall, Hyperventilation, Immediate post-injection reaction, Loss of consciousness, Panic attack

Symptom Text: Patient fell to floor after standing immediately after receiving her first dose of Gardasil. She lost consciousness briefly - approximately 3 seconds. She was disoriented briefly after she regained consciousness, and appeared to have a panic attack type episode with hyperventilation for approximately 10 minutes. She was observed for 15 minutes following the above and fully recovered before leaving the facility with her mother.

Other Meds:

Lab Data:

History: Patient is currently being evaluated by a neurologist for a past fainting episode. An EEG has been done, and the patient and her mother will visit the neurologist this week to discuss results.

Prex Illness: No acute illnesses.

Prex Vax Illns:

Vaers Id: 394687-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Jul-2009	25-Aug-2009	36	09-Aug-2010	11-Aug-2010	NY		20-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2620AA	0	Right arm	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Abnormal sleep-related event, Convulsion, Disorientation, Nocturia, Sleep talking, Snoring, Somnambulism, Tongue biting, Tremor, Unresponsive to stimuli

Symptom Text: Sleepwalking episodes/seizures - nocturnal. The following information was obtained through follow-up and/or provided by the government. 8/11/10 Neurology consultant records received. Service dates 2/15/10 to 6/7/10. Assessment: Nocturnal motor events. Patient has been free of significant nocturnal motor events. Snores, talks in sleep. Occasionally gets up at night to urinate. Physical and neurological examinations are normal. Continue Keppra. 8/17/10 Neurology consultant records received. Service date 1/21/10. Assessment: Seizures. Patient recently found unresponsive at 12:50 AM. Lying on floor with both legs shaking. Bit tongue. Remained unresponsive for 10 minutes, disoriented for 30 minutes. Anticonvulsants, may resume driving after 6 months if seizure free. Do not drink alcohol.

Other Meds: Vitamin - general; Vitamin C

Lab Data: MRI - normal; EEGs - 2 show seizure activity The following information was obtained through follow-up and/or provided by the government. 8/11/10 Labs and Diagnostics: EEG - minimal abnormality. CBC - MCHC 36.8% (H) RDW 11.2% (L). Drug level

History: Sulfa; sport induced asthma The following information was obtained through follow-up and/or provided by the government. 8/17/10 PMH: Trauma to head at 18 months.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **394696-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	09-Aug-2010	09-Aug-2010	0	09-Aug-2010	10-Aug-2010	IL		19-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB382AA		Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0565Z		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Syncope

Symptom Text: TDAP and hepatitis A vaccines were given on right arm and then HPV (GARDASIL) was given on left arm. Patient began looking pale and almost fell off exam table. Patient fainted and was laid down. Patient recovered and went home.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394776-1** **Related reports:** 394776-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Aug-2010	03-Aug-2010	0	10-Aug-2010	11-Aug-2010	LA		03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0414Z	1	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0925Y	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Bell's Palsy, left side of face.

Other Meds: VYVANSE

Lab Data:

History: NKDA; ADHD

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394776-2** **Related reports:** 394776-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Aug-2010	03-Aug-2010	0	24-Aug-2010	26-Aug-2010	LA		31-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0925Y	1	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	04142	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Eye movement disorder, Sensory disturbance

Symptom Text: No feeling on left side of face. Left eye won't close all the way mouth twist when talking, smiling and laughing. She is taking Prednisolone Sod PHO 15mg/5mL, ointment at night so her eye won't dry out.

Other Meds: VYVANSE

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394777-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Aug-2010	04-Aug-2010	0	10-Aug-2010	11-Aug-2010	AZ		12-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB817BA	2	Left arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA		Left arm	Unknown	
MMR	MERCK & CO. INC.	1709Y	1	Unknown	Subcutaneously	
HPV4	MERCK & CO. INC.	1353Y	1	Right arm	Unknown	
IPV	SANOFI PASTEUR	D0039	3	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Feeling hot, Head injury, Loss of consciousness

Symptom Text: Clt given five vaccinations as listed below, following administration of vaccine clt. stated she felt OK. Clt and parent left mobile clinic and when outside in parking lot while trying to get into vehicle; clt "passed out" and fell to ground and sister stated she had hit back of head. Clt mom then brought clt back into mobile and I assessed clt was alert and oriented to person, place, time. Clt stated she felt hot. Fire dept was called and assessed clt and gave parent ok to take clt home and seek medical attention if mental status alters. Parent called on 8/5/10 at 11:30 and stated clt "doing much better today". Clt did not need to seek medical attention.

Other Meds: None

Lab Data:

History: Lymes Disease; Lymphonditis; Testing for Cystic Fibrosis

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394781-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Jul-2010	27-Jul-2010	0	10-Aug-2010	11-Aug-2010	MN		12-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	2	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB382AA	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainting after vaccines.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **394807-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Jan-2009	16-Jan-2009	1	10-Aug-2010	11-Aug-2010	FR	WAES0902USA04405	20-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness, Feeling abnormal, Feeling cold, Listless, Loss of consciousness, Pallor, Presyncope, Vomiting

Symptom Text: Information has been received on 23-FEB-2009 from a Health Authority concerning a 14 year old female patient who on 15-JAN-2009 was vaccinated with a dose of GARDASIL (lot #, batch # not reported) by intramuscular route. On 16-JAN-2009, one day after vaccine administration, the patient had lost consciousness, presented with vomiting, pallor, vasovagal crisis, sensation of cold and dizziness. It was reported that by the 23-JAN-2009 the patient had recovered. The health authority considered vasovagal reaction to be other important medical event. Other business numbers partner numbers include E2009-01640 and ES-AGEMED-2200771341. A corrective version has been created on 10-MAR-2009 in order to correct the start dates of vasovagal reaction and sensation of cold and correct the recovery date. Upon internal review on 04-AUG-2010, the case E2009-01829 was identified as a duplicate. This case (E2009-01829) was considered as the reference case (the oldest one). Number in series, unit dose, action taken with a drug were corrected. Vasovagal reaction was changed to vasovagal attack. As per consolidation date, this case was updated with the follow up information provided in case E2009-01829. It was reported that on the 16-JAN-2009, a day after vaccination, the patient began to feel bad, on the 17-JAN-2009; the patient was taken to the emergency room where she lost consciousness after having experienced dizziness, pallor, cold sensation and vomiting. According to the adverse event box of the report, all the adverse events (except "feel bad" that was not included in the adverse event box, i.e. it was not coded) started on 16-JUN-2009. The patient was sent home with a diagnosis of possible vasovagal attack. The patient did not attend school during that week due to feeling dizzy and listless. Case reported as serious by the HA with other medically important condition as criteria. It was reported that the patient recovered by the 23-JAN-2009. Outcome from feel bad was not reported. Other business partner numbers included E2009-01

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394808-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		10-Aug-2010	11-Aug-2010	FR	WAES1008MEX00001	11-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician concerning an adult female who in approximately 2010 was vaccinated with GARDASIL, she received two doses (specific dates not provided). The reporter referrer that the patient stated that approximately after the second dose was administered she was pregnant and approximately 2 months later the patient experienced abortion (more details not provided). The patient recovered from drug exposure during pregnancy (specific dates not provided). The causality and outcome for abortion were not provided. Upon internal review the abortion was considered as OME. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 01Jan10)

Prex Vax Illns:

Vaers Id: **394811-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Aug-2010	09-Aug-2010	0	10-Aug-2010	10-Aug-2010	OH		11-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C3353AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3336AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB365AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dyskinesia, Heart rate normal, Hyperhidrosis, Immediate post-injection reaction, Musculoskeletal stiffness, Pallor, Syncope

Symptom Text: Client fainted immediately after 4th of 4 vaccines administered. Skin pale, diaphoretic with jerking activity and stiffness of upper extremities. Regained consciousness after being laid prone within seconds. Treatment included monitoring vital signs, positioning prone with legs elevated above heart. Recovery at 45 minutes post administration of vaccines at which time she was sent with mother with instructions if further adverse events should occur. B/P 90/50 at lowest to 100/60 when no further symptoms, pulse 60-64.

Other Meds:

Lab Data: none

History: Allergy to aspirin

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394816-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Aug-2010	09-Aug-2010	0	10-Aug-2010	11-Aug-2010	SC		12-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049CA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3443BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Diarrhoea, Syncope

Symptom Text: Patient fainted, then developed abdominal pain and diarrhea. Patient also on menstrual cycle at visit.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394822-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Jun-2010	15-Jun-2010	0	10-Aug-2010	11-Aug-2010	WI		13-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0075Y	1	Left arm	Intramuscular	HEP

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash pruritic

Symptom Text: Rash on arms and back and slightly pruritic, presented to E room for symptoms. Given BENDARYL 25 mg QID x 3 days on 6-19-2010. Told to return if no improvement.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394831-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Aug-2010	10-Aug-2010	0	10-Aug-2010	11-Aug-2010	CT		13-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	05652	0	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB379BA	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Diarrhoea, Dizziness, Hyperhidrosis, Nausea, Vomiting

Symptom Text: Child had 2 vaccines simultaneously - Hep A and HPV approx 5 min after injections, child felt lightheaded, nausea, stomach cramping-sweats-vomited 3/4 times and had diarrhea - dizzy - was transported to ER for observation.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **394842-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Aug-2010	10-Aug-2010	0	10-Aug-2010	11-Aug-2010	PA		20-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1377Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Lip haemorrhage, Lip swelling, Loss of consciousness, Mouth injury

Symptom Text: Within 5 min of vaccine (GARDASIL) pt passed out onto the floor. Bruise to bridge of nose lower lip cut, scant bleeding, mild swelling.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **394855-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Aug-2010	10-Aug-2010	0	10-Aug-2010	11-Aug-2010	IN		23-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1539Y	2	Left arm	Intramuscular	HEPA MEN

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Nausea

Symptom Text: Immediately after receiving GARDASIL #3 pt. became dizzy, lightheaded, and c/o nausea. Pt. was laid down, feet elevated. Pt. was given cheese crackers and juice, as she denied eating breakfast. Reported previous reaction with other vaccines.

Other Meds: None

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns: SOB - Tachycardia.~Meningococcal Conjugate (Menactra)~1~16.00~Patient|SOB - Tachycardia.~Hep A (Havrix)~1~16.00~Patient

Vaers Id: **394887-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Aug-2010	11-Aug-2010	0	11-Aug-2010	11-Aug-2010	IN		19-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1302Y		Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049BA		Left arm	Intramuscular	
MEN	SANOFI PASTEUR	U3068AA		Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0597Z		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Somnolence, Unresponsive to stimuli

Symptom Text: After patient received vaccines she quietly laid back on couch, did not respond to questions, then woke up and said,"was I sleeping?" Child was given juice and it took approx 20 min before she was able to walk to car.

Other Meds:

Lab Data:

History: none noted

Prex Illness: none noted

Prex Vax Illns:

Vaers Id: **394941-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Jul-2010	22-Jul-2010	1	11-Aug-2010	12-Aug-2010	RI		13-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1333Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pyrexia

Symptom Text: Imm was given 7/21/10. She had a fever for 1 day and a headache for 12 days following the vaccine. No treatment was done.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **394998-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
4.0	M	12-Aug-2010	Unknown		12-Aug-2010	12-Aug-2010	TX		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1013V	0	Right arm	Unknown	
	IPV	SANOFI PASTEUR	D0532	0	Left arm	Unknown	
	HEP	SANOFI PASTEUR	AHBU772DA	0	Right leg	Unknown	
	DTAP	GLAXOSMITHKLINE BIOLOGICALS	C3142AA	0	Left leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administration error, Drug dispensing error

Symptom Text: Office staff member incorrectly selected the Human Papillomavirus Quadrivalent, rather than the Intrapulmonary percussive ventilators (IPV), and handed it to MA who then administered the vaccine.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **395001-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-Aug-2010	13-Aug-2010	AR	WAES1008USA00478	13-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a teenager female who on an unspecified date was vaccinated with GARDASIL (therapy dose, route and site unknown). Subsequently the patient experienced seizure. The patient sought unspecified medical attention. On an unknown date, the patient recovered from seizure. Upon internal review, seizure was considered to be an other important medical event. This is one of several reports from the same source. The health care professional contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination, dose number, lot number, date of event, and hospital name (if applicable). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **395027-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	29-Jul-2010	29-Jul-2010	0	12-Aug-2010	13-Aug-2010	TX	TX20100080	13-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	SANOFI PASTEUR	U3016AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1316Y	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dry skin, Erythema, Skin warm, Throat irritation

Symptom Text: 9:05 MON STATED NOTED CLIENTS NOSE GOT RED. CLIENT COMPLAINED OF ITCHING TO THROAT, CLEARING THROAT. 911 CALLED. VIS 121/70, P85 RESP20 SKIN WARM AND DRY TO TOUCH. NO SOB NOTED. 9:15 121/73, P88, RESP 20 9:25 129/86, P84 RESP 20. CLIENT STATED FEELS BETTER. MOM AND CLIENT THEN STATED CLIENT HAS SEASONAL ALLERGIES TO ENVIRONMENT, TAKEN CLARITIN 2 DAYS AGO. 9:40 VIS 129-84, P88, RESP 20. MOM REFUSED TO WAIT FOR AMBULANCE, STATED WOULD TAKE TO MD IF NEEDED. CLIENT ESCORTED BY NURSE TO CAR. NO SOB, CONVERSIVE ABOUT VIDEO GAMES. ALERT.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **395029-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Aug-2010	10-Aug-2010	0	12-Aug-2010	13-Aug-2010	TX	TX20100082PU	13-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0261Y	2	Left arm	Intramuscular	
MEN	SANOFI PASTEUR	U3101AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B042BA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1748Y	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: AFTER RECEIVING VACCINES, CLIENT EXPERIENCED SYNCOPE, REMAINED IN CHAIR, APPEARED TO FAINT FOR +/- 2 SECONDS, CAME TO QUICKLY. BY 20 MINUTES HAD RECOVERED FROM EVENT. TOOK B/PX4 GAVE SNACK AND WATER.

Other Meds: NONE

Lab Data: NONE

History: TETRACYCLINE TYPE ALLERGY

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395033-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	10-Aug-2010	10-Aug-2010	0	12-Aug-2010	13-Aug-2010	CO		13-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3339AA	0	Right arm	Intramuscular	
MMR	MERCK & CO. INC.	1623Y	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0597Z	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1559Y	1	Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB379AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site erythema, Injection site nodule, Injection site rash, Injection site swelling, Pyrexia, Syncope

Symptom Text: Per mother of child, patient felt faint and dizzy upon leaving clinic. That evening around 5:00 pm, patient fainted when with Uncle. Family did not seek medical attention and states patient was fine after fainting. Mother noticed on 8/11/10 that patient had a knot on right tricep at injection site with some swelling. Applied heat pack to site. Bicep and tricep continued to swell and red band appeared around bicep and tricep on 8/12/10. Red rash around injection site on right tricep appears to be size of silver dollar per mother of child as of 8/12/10. Mother states patient had low-grade fever on 8/11/10 and treated with Tylenol. Mother of child states the injection site is not have pus or drainage and only appears to have swelling and redness. Instructed mother of child to follow up with doctor.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395040-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	03-Aug-2010	03-Aug-2010	0	12-Aug-2010	13-Aug-2010	NM		13-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	
	PPV	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Injection site warmth, Tenderness

Symptom Text: Pain, Swelling, heat to area of administration, Tenderness throughout lateral deltoid and axilla.

Other Meds:

Lab Data:

History: Asthma Knee pain Viral respiratory infection

Prex Illness: viral upper respiratory infection Knee pain Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395051-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Aug-2010	12-Aug-2010	0	12-Aug-2010	13-Aug-2010	PA		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3446AA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3465AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0565Z	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Syncope

Symptom Text: After receiving vaccines, pt with syncope-lying down on table, pale, out for approximately 20 sec feet were raised; HR=60; BP 98/62; PT given lollipop and soda to drink (Pt did not have anything to drink or eat prior to vaccine administration). Pt stayed in office for 20 min-HR=60 BP 102/70. Pt walked out of office accompanied by mother.

Other Meds: None

Lab Data:

History: Functional murmur

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395057-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Aug-2010	11-Aug-2010	0	12-Aug-2010	13-Aug-2010	TN		16-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1539Y	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Lethargy, Ocular hyperaemia, Tremor

Symptom Text: After injection she stood up at sat down of stool in room she began to slump over. Father caught her and eased her to floor. Ammonia used pt lethargic RN and father of pt lifted her to exam table. Her eyes were bloodshot sclera red bilateral very shaky BP. 100/60 pulse regular. Lethargic but oriented to place and person. 911 called for transport to ER.

Other Meds: None.

Lab Data: Hgb 14.1; BP 100/60; 120/70 5 min later; pulse regular

History: Allergic to PCN and CECLOR.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395074-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Aug-2010	12-Aug-2010	0	13-Aug-2010	17-Aug-2010	IL		24-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0605Z	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U3511AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0664Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Hypotonia, Malaise, Tonic clonic movements, Unresponsive to stimuli

Symptom Text: Approx 5 min after receiving vaccines c/o "I don't feel well". Was sitting in chair - put head between knees - sat up and then went limp in dad's arms who was standing at side of chair. Placed on exam table - was unresponsive for approx 2 1/2 - 3 minutes when placed on table remained unresponsive. Then started with clonic/tonic type movement to arms- were curled up besides body- no incontinence or rolling of eyes but appeared to be seizure. Apparent seizure lasted approx. 2 minutes 911 was called at onset of going limp- Dr called to examining room and witnessed seizure. Transported to Medical Center for evaluation per Fire Dept.

Other Meds: No meds.

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2010	13-Aug-2010	1	13-Aug-2010	17-Aug-2010	KY		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pyrexia

Symptom Text: C/o fever and headache. Advised to take TYLENOL or ibuprofen and FU with MD.

Other Meds: None

Lab Data:

History: Allergy to Amoxicillin

Prex Illness: None

Prex Vax Illns:

Vaers Id: **395122-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	01-Jan-2010		13-Aug-2010	16-Aug-2010	FR	WAES1008USA00075	25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical conisation, Cervical dysplasia, Cervix carcinoma stage 0, Chlamydia test negative, Human papilloma virus test negative

Symptom Text: Case received from a gynecologist on 16-JUL-2010. Case medically confirmed. A 20 year old female patient was found to have PAP IIId in January 2010 after receiving a complete vaccination series with three doses of GARDASIL IM into the upper arm in 2007 when she was approximately 16 years old. On 03-MAY-2010 she was found to have PAP IVa. HPV test and smear for Chlamydia and other infections were negative. On 01-JUN-2010 conisation was performed. History showed CIN II of squamous epithelium (resection in sano) and molecular pathologic test was again negative for HPV. The patient recovered within an unspecified time. Follow up information has been received on 06-AUG-2010. Corrective version. Upon internal medical review the case was upgraded to serious (cervical conisation considered as invasive treatment/other medically important event). File is closed. Case was linked with E2010-04305 (WAES # 1008USA00076). Other business partner numbers included E2010-04302. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395123-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Jul-2010	30-Jul-2010	0	13-Aug-2010	16-Aug-2010	FR	WAES1008USA01067	24-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ37220	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Nausea, No reaction on previous exposure to drug, Pain, Pyrexia, Vomiting

Symptom Text: Information has been received from a health professional and the patient's mother concerning a 15 year old female patient who on 01-JUN-2010, was vaccinated with the first dose of GARDASIL (lot # NJ37220, Batch NK51050). No adverse effect followed this vaccination. On 30-JUL-2010, the patient was vaccinated with the second dose of GARDASIL (lot # NJ37220, Batch NK51050, route not reported). In the same day as vaccination, 30-JUL-2010, the patient developed fever, 39 degree C for five days and nausea. Later on the patient vomited (in July 2010), the patient felt dizzy and experienced feeling of convulsion in body and body pain (specific dates of onset in August 2010 not reported). On 04-AUG-2010, the patient visited the doctor for investigation. There was no signs of infection and the SR was normal. It was considered that the symptoms were related to GARDASIL. case medically confirmed. On 05-AUG-2010, the patient felt better for the first time. The patient's outcome was recovering. The case was reported as non serious by the patient's mother and HCP. After medical revision by the company, the case was considered to be upgraded to serious as other important medical event. The case is closed. Other business partner included E2010-04590. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395124-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Oct-2009	03-Nov-2009	7	13-Aug-2010	16-Aug-2010	MI	WAES1006USA01644	25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Headache, Lymphadenopathy, Malaise

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with no known drug reactions/allergies and no known medical history who in August 2009 and in October 2009, was vaccinated with the first and second dose of GARDASIL, respectively. Concomitant therapy included amitriptyline hydrochloride (MSD). In 2009, "a few months after the second dose", the daughter began experiencing headaches. Magnetic resonance imaging (MRI) was conducted (results not reported). The mother mentioned that the doctor who began treating her daughter with the headaches suggested she should not get the third dose and the consumer decided not to. At the time of reporting, the outcome of headaches was unknown. The patient sought unspecified medical attention. Follow up information was received from a physician's assistant who reported that on 17-JUL-2009 and 27-OCT-2009, the 14 year old (also reported as 15 year old) patient was vaccinated with the first and second dose of GARDASIL, respectively. There was no illness at time of vaccination. On 03-NOV-2009, the patient experienced headaches constant, generally feeling unwell, swollen glands and stomach aches. The patient was seeing a neurologist and headache specialist. A MRI was performed which showed normal results. At the time of reporting, the patient was not recovered. Headache constant, generally feeling unwell, swollen glands and stomach aches were considered to be other important medical events due to requiring medical/surgical intervention by the reporter. Additional information has been requested.

Other Meds: ELAVIL

Lab Data: Magnetic resonance, normal results

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395125-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	09-Jul-2010	Unknown		13-Aug-2010	16-Aug-2010	--	WAES1007USA02894	25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed nurse practitioner, for GARDASIL, a Pregnancy Registry product, concerning a 24 year old female pregnant patient (last menstrual period was 15-JUN-2010) with no known drug reactions, allergies or pertinent medical history who on 09-JUL-2010 was vaccinated IM with a first dose of GARDASIL (lot number 663559/1178Y). The nurse reported that an urine pregnancy test was performed but the positive pregnancy indicator was so light that it was missed and the dose of GARDASIL was given. No known adverse effects were reported. Estimated delivery date is 25-MAR-2011. Follow up information has been received from the nurse practitioner who reported that the patient decided to electively terminate the pregnancy. The nurse reported that the patient would be having the procedure done on 05-AUG-2010. The nurse also reported that the termination was not vaccine related. The nurse reported that the patient "just did not want the pregnancy". At the time of the report that patient's outcome was unknown. Upon internal review "the patient decided to electively terminate the pregnancy" was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: urine beta-human, 07/09/10, pregnancy, the indicator was so light that it was missed

History:

Prex Illness: Pregnancy NOS (LMP = 6/15/2010)

Prex Vax Illns:

Vaers Id: **395144-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Sep-2007	18-Sep-2007	8	13-Aug-2010	16-Aug-2010	FR	WAES0806USA02183	27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1539F	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness, Gait disturbance, Hypokinesia, Muscle spasms, Myalgia, Nausea, Oedema peripheral, Pain, Panic attack, Presyncope, Syncope, Vaccine positive rechallenge, Visual impairment

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 10-SEP-2007 was vaccinated intramuscularly in the upper arm with her first dose of GARDASIL (Lot # 1539F; Batch NF42170). On 10-NOV-2007, also reported as 2 months after the first dose, the patient experienced myalgia (duration not reported). On 12-NOV-2007, the patient was vaccinated intramuscularly in the upper arm with her second dose of GARDASIL (Lot # 0354U; Batch NF58150). On 31-MAR-2008, the patient was vaccinated intramuscularly in the upper arm with her third dose of GARDASIL (Lot # 0510U; Batch NG20180). On approximately 21-APR-2008, also reported as "about 3 weeks post vaccination" of the third dose, the patient complained of myalgia of both thighs on exertion which occurred immediately after "presyncopal events" with dizziness and nausea. These "attacks" relapsed several times. On 30-APR-2008, the patient consulted an outpatient neurological department. Physical examination showed normal results. No measures were taken. As symptoms were ongoing, the patient was hospitalized on 07-MAY-2008 for clarification. During the physical neurological examination, the patient complained of pain in both thighs and reduced movements of both legs. An MRI of spine, cranial MRI and cerebrospinal fluid showed normal results. Laboratory tests, including "BSR" (see lab data section) showed normal findings. Serology for Borrelia showed "questionable positive result for IgM", IgG was negative. Antibodies against enterovirus, varicella zoster virus, CMV and HSV were all negative for blood and CSF. On 09-MAY-2008, the patient was discharged from the hospital. At the time of reporting she had not yet recovered. The reporting pediatrician assessed a causal relation between the adverse event and dose 1 and dose 3 vaccinations as "possible". The second dose of GARDASIL dose 2 was well tolerated. Follow-up information was received on 21-AUG-2008 which reported that the patient recovered from presyncope, nausea and dizziness, but she is still suf

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 07May08, normal; magnetic resonance imaging, normal; APTT, 07May08, normal; hematocrit, 07May08, normal; hemoglobin, 07May08, normal; platelet estimate, 07May08, normal; serum C-reactive protein, 07May08, normal;

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **395159-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Aug-2009	13-Aug-2009	1	13-Aug-2010	17-Aug-2010	FL		24-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: Pt had swelling of both hands on following day, BENADRYL helped. Had received vaccine 8/12/09, notified us on 8/9/10 when seen for physical.

Other Meds: SINGULAIR; ADVAIR; Albuterol

Lab Data:

History: Allergic to dairy; had Kawasaki in past; asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395168-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Aug-2010	11-Aug-2010	1	13-Aug-2010	17-Aug-2010	CA		19-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1316Y		Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B054BA		Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion, Erythema, Skin warm, Swelling

Symptom Text: Pt. came in at 8:59, bruised, swollen, redness and hot. Seen by MD and advised to apply cold compresses, and if worsens to return.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395180-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	05-Aug-2010	05-Aug-2010	0	13-Aug-2010	17-Aug-2010	MA		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1495Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted about 3 minutes after receiving her 3rd dose of Gardasil. She did not lose consciousness. She had not eaten at all that day. Was given juice. VS were stable.

Other Meds:

Lab Data:

History: no

Prex Illness: No

Prex Vax Illns:

Vaers Id: **395199-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	13-Aug-2010	13-Aug-2010	0	13-Aug-2010	17-Aug-2010	IL		24-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0096Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Nervousness, Tinnitus

Symptom Text: Pt was administered 1st series of Gardasil vaccine at 10:49 AM. After sitting in the waiting area for about 5 minutes pt c/o nausea, ringing in ears, feeling "shakey". Pt was escorted to exam table and instructed to rest until she felt better. Vital signs were taken and were stable. Pt was evaluated by Dr. and released after about 10 minutes without limitations.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395202-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	M	13-Aug-2010	13-Aug-2010	0	13-Aug-2010	17-Aug-2010	FL		24-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0318Z	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB431AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3035CA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395209-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	29-Jun-2010	29-Jun-2010	0	13-Aug-2010	16-Aug-2010	MI		19-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1316Y	0	Right arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP110AA	0	Left arm	Intramuscular	
	PPV	MERCK & CO. INC.	0509Y	0	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain

Symptom Text: 2.5" X 3" REDDENED AREA ON RIGHT DELTOID, SORE TO TOUCH

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **395220-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Jun-2009	01-Jun-2009	0	14-Aug-2010	17-Aug-2010	AZ		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0100Y	2	Left arm	Intramuscular	HPV4
							HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breech presentation, Caesarean section, Depression, Dizziness, Headache, Hypertension, Hypoaesthesia, Injection site pain, Nausea, Paraesthesia, Premature labour, Premature rupture of membranes, Syncope, Vomiting

Symptom Text: Pain at injection site, numbness and tingling in arms and fingers, syncope, dizziness, nausea and vomiting, frequent headaches after the vaccine up till feb 2010. Currently I still experience numbness and tingling in my arms and fingers, nausea, and frequent headaches. The following information was obtained through follow-up and/or provided by the government. 8/16/10 Received PCP medical records for service date 2/11/2010. Assessment: HTN, obesity, depression. 8/30/10 Received hospital medical records for 1/4-1/6/2010. FINAL DX: PROM, premature delivery 32wk, c-section for frank breech presentation, problematic fetal heart rate G2, P1, Ab1 EDD 2/26/10

Other Meds: none

Lab Data: n/a The following information was obtained through follow-up and/or provided by the government. 8/30/10 Received medical records w/LABS: WBC 20.2(H), ANC 17.1(H), abs mono 1.3(H). calcium 8.2(L), albumin 32.5(L)

History: My self only had sesonal allergies The following information was obtained through follow-up and/or provided by the government. 8/30/10 Received medical records w/PMH: morbid obesity,

Prex Illness: none

Prex Vax Illns: son born with birth defects~HPV (Gardasil)~3~24.92~Patient

Vaers Id: **395224-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Jul-2010	05-Aug-2010	15	15-Aug-2010	17-Aug-2010	GA		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Face oedema, Oedema peripheral, Pruritus, Rash pustular, Urticaria

Symptom Text: Hives, rapid edema on hands and face, itching raised rash on thighs with individual pustules.

Other Meds: Lamictal, PEN

Lab Data:

History: Depression

Prex Illness: Swollen tonsils

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395274-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	M	09-Aug-2010	11-Aug-2010	2	16-Aug-2010	17-Aug-2010	CT		17-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061CA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	06642	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Fatigue, Lethargy, Malaise, Throat tightness, Wrong drug administered

Symptom Text: Tightness and sensation of obstruction in throat, coughing, feeling of illness, lethargy, unusual tiredness.

Other Meds: None

Lab Data: NONE! Dr. insisted the symptoms were unrelated to the vaccination, was unaware that these symptoms are even on the PI or patient information guide.

History: Erythromycin

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395275-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Aug-2010	12-Aug-2010	0	16-Aug-2010	17-Aug-2010	TX		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3362AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1333Y	0	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	C3446AA		Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	0344Z	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, Immediate post-injection reaction, Postictal state

Symptom Text: This 15yo female had generalized tonic seizure lasting 30 seconds immediately after receiving HPV vaccine. She recovered fully with post-ictal state w/in 5 minutes.

Other Meds:

Lab Data: Normal vitals/oxygen saturation

History: None

Prex Illness: None

Prex Vax Illns: Dizziness/fainting w/previous vaccinations~Vaccine not specified (no brand name)~UN~0.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395278-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Feb-2010	Unknown		16-Aug-2010	17-Aug-2010	MI		23-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Pt was seen for a regular physical exam on the 23rd February 2010 during which time GARDASIL was administered. Later it was found that she was pregnant and her EDC is 8/15/2010.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395328-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Aug-2010	03-Aug-2010	0	16-Aug-2010	17-Aug-2010	IA		23-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1539Y	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Malaise, Pyrexia

Symptom Text: Malaise fever started 3 pm. IBU & TYLENOL BACTRIM DS

Other Meds: None

Lab Data: Urinalysis

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395340-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Aug-2010	12-Aug-2010	0	16-Aug-2010	17-Aug-2010	TN		19-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0341Z	1	Left arm	Subcutaneously	
TDAP	SANOFI PASTEUR	C3448AA	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0819Y	0	Left leg	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB401AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia

Symptom Text: Pt reported (R) arm jerking within 15 minutes of getting vaccine in (R) upper arm. 8-13-09 F/U at ph # given per dad. Spoke with G.M. "pt went to school today" "ok as far as she is aware".

Other Meds:

Lab Data:

History: None noted.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **395348-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Aug-2010	11-Aug-2010	0	16-Aug-2010	17-Aug-2010	NY		20-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0091Z	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Vaccination site erythema, Vaccination site oedema

Symptom Text: Edema, erythema and itch on upper right arm at site of vaccine.

Other Meds:

Lab Data:

History:

Prex Illness: UTI

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395356-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Aug-2010	Unknown		16-Aug-2010	17-Aug-2010	OK		24-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3446AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0094Z	0	Right arm	Subcutaneously	
	MEN	SANOFI PASTEUR	U3076AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Mother returned with client 8/16/10 and reported that patient is 6 weeks pregnant. They are worried about any adverse reactions that may occur with the unborn child.

Other Meds: N/A

Lab Data: N/A

History: None Noted

Prex Illness: None Noted

Prex Vax Illns:

Vaers Id: **395358-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	05-Aug-2010	05-Aug-2010	0	16-Aug-2010	17-Aug-2010	KS		24-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0338Z	1	Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061CA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3362AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1354Y	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB431AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Syncope

Symptom Text: 10 minutes after shots given patient had dizziness, seizure, and fainting for approximately 1 minute. Patient recovered after ammonia inhalant given. No falling, no injury. Blood pressure 98/60, pulse = 58. 911 called and pt. taken to hospital.

Other Meds: No

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395364-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Aug-2010	13-Aug-2010	0	16-Aug-2010	17-Aug-2010	CA		17-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Nausea, Syncope, Throat tightness

Symptom Text: Received first injection of GARDASIL. Suffered throat constriction and inability to breathe; nausea; fainting. Patient reported later it was unlike asthma attack, which affects chest. This was throat constriction. Two puffs of albuterol did not help; symptoms fortunately abated and patient recovered on own.

Other Meds:

Lab Data:

History: exercise-induced asthma

Prex Illness: cold/congestion

Prex Vax Illns:

Vaers Id: **395393-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Aug-2010	18-Aug-2010	US	WAES1008USA01104	03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Deafness

Symptom Text: Information has been received from a physician. The physician recommended one of her patients to receive GARDASIL, but the patient's mother said no because one of her friends who was a physician, their daughter received a dose of GARDASIL, and subsequently experienced deaf. At the time of reporting, the outcome was unknown. It is unknown if the patient sought medical attention. Upon internal review, deaf was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395394-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		17-Aug-2010	18-Aug-2010	US	WAES1008USA01126	03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female patient with no pertinent medical history who on an unknown date was vaccinated with her first dose of GARDASIL. About 6 hours after receiving her first dose of GARDASIL, the patient developed shortness of breath. She went to the Emergency Room but was not admitted to the hospital. No specific treatment was given. The patient had gone to two different doctors and was still experiencing symptoms. The reporting registered nurse considered "shortness of breath" to be an other important medical event due to visit to the Emergency Room. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395404-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Aug-2010	14-Aug-2010	0	17-Aug-2010	17-Aug-2010	IL		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1778Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Grand mal convulsion, Head injury, Headache, Hyperhidrosis, Oropharyngeal pain

Symptom Text: Patient had generalized tonic clonic seizure lasting approximately 5 seconds a few minutes after receiving GARDASIL #1. This was followed by dizziness, diaphoresis, sore throat & headache. Patient may have hit head against wall during the seizure.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395408-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Dec-2007	Unknown		17-Aug-2010	17-Aug-2010	OK		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection

Symptom Text: 1st pap: 7/21/2010 @ 17 y.o. results = low grade squamous intraepithelial lesion (C1NI/HPV effect).

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **395428-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Aug-2007	Unknown		17-Aug-2010	18-Aug-2010	US		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0469U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breast enlargement

Symptom Text: Mom alleges that childs breast asymmetry (Rt breast larger) was caused by HPV vaccine?

Other Meds:

Lab Data:

History: had breast asymmetry prior to HPV #1

Prex Illness: none

Prex Vax Illns: ~HPV (no brand name)~3~15.00~Patient|~HPV (no brand name)~3~12.00~Sibling

Vaers Id: **395430-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	25-Feb-2008	Unknown		17-Aug-2010	18-Aug-2010	MI		03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB171AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breast malformation

Symptom Text: Mom alleges that child's breast asymmetry was caused by HPV vaccine (left breast smaller).?

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: ~HPV (no brand name)~3~12.00~Patient|~HPV (no brand name)~3~15.00~Sibling

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395455-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Aug-2010	16-Aug-2010	0	17-Aug-2010	18-Aug-2010	SC		23-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1332Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: C/o felt light headed, after telling her mom this pt took off in a run. Pt found in floor a few feet away from checkout desk, this occurred within 10 min of receiving vaccine for HPV GARDASIL. Pt assisted to w/c and rested in treatment room. BP originally 94/34 after resting a few minutes 100/70. Checked by office PNP and released home with mom.

Other Meds: Concerta

Lab Data:

History: NKDA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395461-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Aug-2010	10-Aug-2010	1	17-Aug-2010	18-Aug-2010	FL		03-Sep-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1332Y	0	Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	B379BA	0	Right arm	Unknown	
IPV	SANOFI PASTEUR	D04801	4	Left arm	Unknown	
TTOX	SANOFI PASTEUR	U3006EA	2	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U3355BA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hyperhidrosis, Pallor, Unresponsive to stimuli

Symptom Text: During the process of vaccinating the client with HPV,she became pale, diaphoretic and non compliant to verbal orders. Cold water compress was applied to neck and face, Vital signs were obtained. Paitent was given orange juice prior to immunizations after admitting not eating that A.M. A second can of orange juice was given after patient bacame more responsive. Patient was walked to alternate room and allowed to lie down until she felt better. Patient left with Guardian under own power.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395476-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	04-Aug-2010	06-Aug-2010	2	17-Aug-2010	18-Aug-2010	UT		03-Sep-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	100004	0	Right leg	Unknown	
HPV4	MERCK & CO. INC.	0318Z	0	Right leg	Unknown	
HEPA	MERCK & CO. INC.	0415Z	1	Left leg	Unknown	
TDAP	SANOFI PASTEUR	U3082CA	5	Left leg	Unknown	
VARCEL	MERCK & CO. INC.	1749Y	1	Left leg	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Injection site erythema, Injection site swelling, Injection site urticaria, Injection site warmth

Symptom Text: (L) thigh, welt 3 1/2 x 4 1/2 wide red, hot to touch, swollen. Cold packs Ibuprofen and TYLENOL, Heat packs, trouble breathing x 4 days treated w/antibiotic.

Other Meds: None

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **395484-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Aug-2010	12-Aug-2010	2	17-Aug-2010	18-Aug-2010	AL		26-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3056AA	0	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB437AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3356AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Pain, Swelling

Symptom Text: 12 yo female with increased redness, swelling induration 48 hrs after vaccine given- (Tdap) with increased pain. 3.2 x 4.5cm area of induration no redness no fever.

Other Meds: None

Lab Data:

History: Seasonal allergies

Prex Illness:

Prex Vax Illns:

Vaers Id: **395489-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Jun-2010	09-Jun-2010	1	17-Aug-2010	18-Aug-2010	FL		26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1332Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised, Rash pruritic, Skin discolouration

Symptom Text: Black rash all over body the day after immunization (itchy rash).

Other Meds:

Lab Data:

History: Diabetes

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395491-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Aug-2010	13-Aug-2010	0	17-Aug-2010	18-Aug-2010	OH		24-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487Y	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Hyperaesthesia, Pruritus, Pruritus generalised, Rash erythematous, Skin burning sensation

Symptom Text: Itching starting on feet, progressed to red rash and generalized itching. Pruritis eventually waxing and waning. I saw pt on 8/17 and there was no rash remaining. Patient also complained of skin sensitivity and burning, which had resolved by 8/17. She had a headache on 8/15.

Other Meds: none

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

Vaers Id: **395494-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Aug-2010	17-Aug-2010	0	17-Aug-2010	18-Aug-2010	GA		02-Sep-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3340AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0249Y	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB427BA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0068Z	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Muscle rigidity, Tonic clonic movements, Tremor

Symptom Text: After being immunized with Varivax, Hep A, Menactra & Gardasil, patient's eyes rolled back, upper ext shook with tonic-clonic activity and legs became rigid. Within 2 minutes eyes were fluttering and patient was alert.

Other Meds: none

Lab Data: none

History: hx syncope with hot curling iron in early childhood

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395499-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Aug-2010	13-Aug-2010	0	17-Aug-2010	18-Aug-2010	AR		18-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Headache, Lethargy, Muscle rigidity, Pyrexia, Syncope, Tremor, Visual impairment

Symptom Text: Shortly after vaccine was given, the patient fainted with jerking seizure like movements, body rigidty with feet turned inward and shaking. After coming too she said that prior to fainting she saw flashes of colored lights in her eyes-colors of pink and blue. She came too and appeared fine, but scared and shaky. That night and for 2 days she ran low grade fever, was very lethargic and complained of headache. It has been four days and she still doesn't seem her normal energetic self, and she seems to have complaints of a headache daily.

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395500-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2010	13-Aug-2010	1	17-Aug-2010	18-Aug-2010	IN		20-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0671Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3088AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Malaise, Neuralgia, Pain

Symptom Text: bilateral arm neuralgia, achy bones, general malaise, flu like symptoms, only more deep set ache

Other Meds:

Lab Data:

History: none that would prevent vaccination

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395503-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	12-Aug-2009	09-Nov-2009	89	18-Aug-2010	18-Aug-2010	MN		18-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0812Y	1	Left arm	Unknown	
MEN	SANOFI PASTEUR	U2992AA	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0216Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Dysmenorrhoea, Fatigue, Headache, Hypersomnia, Hypoaesthesia, Injection site pain, Menorrhagia, Muscle spasms, Nausea, Pain in extremity, Photophobia, Rash, Tremor, Vomiting

Symptom Text: These are the following symptoms that she has complained of since getting the shot. Not all of them are every day but she's had them throughout this past winter and now: Fatigue-especially after exertion ie: tennis, phyed, snowmobiling, wakeboarding, snowboarding, she's been checked for anemia, ekg, mono, liver test, kidney test, blood counts etc.. all come back normal. It is hard to wake her during some of these episodes. She doesn't want to drive, instead tends to sleep in car if it's more than a 20 minute ride. Headaches in the last month have been most everyday now. Vomiting- when not "feeling right" as she puts it she will vomit once and then will sleep alot. Light sensitivity- was complaining of this when she'd walk out of school also says her vision is worse. Stomach gets very nauseous and sometimes cramping pain. Shaky at times then feels better later. Gets a rash that comes and goes on her chest. Complained of arm hurting and burning for a few days after the shot. Back ache and leg pain. Cramping more with periods, periods are very heavy, which she was put on the pill in Feb. for. About a month ago she had an episode at mass that her fingers/hand was numb. The feeling did come back though.

Other Meds:

Lab Data: She also got the Menectra shot and chicken pox shot on the same day as her first Gardasil shot. The following blood test have been done and all are in normal range except Vitamin D which was at 26. Celiac Panel, Lyme Disease, Comprehans

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395507-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Aug-2010	17-Aug-2010	0	18-Aug-2010	18-Aug-2010	VA		03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3443BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0787Z	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB427BA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3352BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Unresponsive to stimuli

Symptom Text: Patient received vaccines approx 0920-0925: 4 shots 2 on each deltoid. After receiving vaccines patient complained of feeling dizzy. Rested on table in exam room in 5-7 minutes, when questioned: Patient stated she felt fine. Patient escorted to chair seated with dad in 0945 noticed patient to have laid head back in chair with hands in a fist unresponsive quickly brought patient to floor and she awaken right away.

Other Meds: None

Lab Data: Neurological examination

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395511-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	11-Aug-2010	11-Aug-2010	0	18-Aug-2010	18-Aug-2010	IN		03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049BA	5	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Hypoaesthesia, Oedema peripheral, Tenderness

Symptom Text: Left arm swollen, red, tender, some complaints of numbness. has appt to see the doctor this morning 8/13/10. Has been giving ibuprophen and applying ice to arm.

Other Meds:

Lab Data:

History: Penicillin, grapes, apples, kiwi

Prex Illness: no

Prex Vax Illns:

Vaers Id: **395520-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Jul-2010	27-Jul-2010	1	18-Aug-2010	19-Aug-2010	CA	WAES1008USA01102	31-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3089AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1178Y		Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	U3042CA		Unknown	Unknown	
	HEPA	MERCK & CO. INC.	0245Z		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling abnormal, Loss of consciousness, Pallor, Resuscitation, Syncope

Symptom Text: Information has been received from a physician concerning an 11 year old female patient who on 26-JUL-2010 was vaccinated intramuscularly with a 0.5ml dose of GARDASIL (lot# 663559/1178Y). Vaccination on the same date also included a dose of VAQTA (MSD) (lot# not reported), a dose of MENACTRA and a dose of ADACEL. On 27-JUL-2010 the patient passed out and was pale and lifeless. The patient's father performed CPR and took her to the Emergency Room. At the time of this report, the patient had recovered. The patient's events were considered to be other important medical events by the reporter because the patient's father performed CPR. Follow-up information has been received from a medical assistant in the physician's office. The MA reported that the 11 year old female was with concurrent condition of asthma and was allergic to SEPTRA and AUGMENTIN. The patient on 26-JUL-2010 was vaccinated with VAQTA (MSD) (lot# 667262/0245Z), MENACTRA (lot# U3089AA) and ADACEL (lot# U3042CA). Concomitant therapy included albuterol inhaler. Onset of the event was the day after the vaccines were administered. On 27-JUL-2010 the patient was at home and passed out. The father performed CPR, although not needed. The patient was taken to Emergency room. Unknown what diagnostics were performed or what treatment was given. No further information is available. The following information was obtained through follow-up and/or provided by the government. 8/26/10 ER records and labs and diagnostics received for date of service 7/27/10. Dx: Syncope. Presented to the ER after a syncope episode lasting 20-30 seconds. Discharged in stable, improved condition.

Other Meds: albuterol

Lab Data: Unknown The following information was obtained through follow-up and/or provided by the government. 8/19/10 Received medical records w/LABS: Neutros 80.2%(H), lymphs 13.6%(L). CT head & EKG WNL. 8/26/10 ER records and labs and diagnostics

History:

Prex Illness: asthma; sulfonamide allergy; allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395557-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	12-Aug-2010	13-Aug-2010	1	18-Aug-2010	18-Aug-2010	AL	AL1021	19-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3353AA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3074AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1099Y		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1704Y		Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diet refusal, Feeling abnormal, Nausea, Oedema peripheral, Pain in extremity, Pyrexia

Symptom Text: 4:30 AM T-103.5, Rt. arm swollen and sore, mom giving Advil 200mg q6 hr. for fever, c/o nausea, will not eat or drink. Feels real bad according to mom referred to MD or ER for eval of fever. 103-104 and feeling really bad.

Other Meds:

Lab Data:

History: Denies

Prex Illness: Denies

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395580-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	14-Jul-2010	14-Jul-2010	0	18-Aug-2010	19-Aug-2010	TX		19-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0318Z	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Headache, Hyperhidrosis

Symptom Text: Patient called the office on 8/17/2010 to report complaints of feeling hot, excessive sweating, and increased headaches since receiving Gardasil on 7/14/2010. She was referred to her primary care physician for further evaluation.

Other Meds: Advair, albuterol, Anaprox DS

Lab Data: none

History: asthma, HSV I, endometriosis

Prex Illness: no acute illness

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395595-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	24-Jun-2010	13-Aug-2010	50	18-Aug-2010	19-Aug-2010	ID		19-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3077AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3353AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1558Y	0	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Herpes zoster, Mobility decreased, Musculoskeletal pain, Rash

Symptom Text: Started having pain in right shoulder on 8/13. On 8/15 developed a red rash on right shoulder and arm. Pain increased. Saw MD on 8/15/10, diagnosed herpes zoster, started on Acyclovir 800mg 5x daily. 8/16 Parent reports severe pain and limited mobility of right shoulder/arm.

Other Meds: Unknown

Lab Data:

History: NO

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Dec-2009	01-Feb-2010	62	19-Aug-2010	20-Aug-2010	FR	WAES1008MEX00006	20-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a female who in approximately December 2009 completed her schedule vaccine, she was vaccinated with GARDASIL 3rd dose. In February 2010, the patient experienced cervical intraepithelial neoplasia. The reporter referred previously Papanicolaou test were normal. Approximately in February 2010 was performed a colposcopy that reported as NIC 1, following was performed a biopsy (with four samples) that reported as NIC 1 and finally a cervix conization was performed that reported as NIC 3. The causality and outcome were reported as unknown. Upon internal review that cervical intraepithelial neoplasia was considered as cancer and other medical event. After several attempts we couldn't to contact the physician to obtain more information. No further information is available.

Other Meds: Unknown

Lab Data: colposcopy, ??Feb10, nic 1; biopsy, ?Feb10, with four samples, reported as nic 1; cervix conization, ??Feb10, nic 3; Pap test, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395806-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Jul-2010	27-Jul-2010	0	19-Aug-2010	20-Aug-2010	FR	WAES1008USA01451	20-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ39080		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysphonia, Pruritus, Rash papular

Symptom Text: Information has been received from a Health Authority (HA) (case n. 121248, local case n. IT353/10) concerning a 16 year old female patient who was vaccinated on 27-JUL-2010 with one dose of GARDASIL (lot number NJ39080, batch number NL18100) IM. On the same day, 1 hour post-vaccination, she presented with small itchy papulae localized mainly on the limbs and face and alteration of the voice. She was treated with SOLUCORTEF, RANIDIL, and TRIMETON 1 vial IM and 4 mg compress 2 times daily for 7 days. At the time of reporting the patient's condition had improved. The final outcome was not reported. Upon internal review the patient was treated with SOLUCORTEF was considered to be an other important medical event. Other business partner numbers include: E2010-04552. The case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 395808-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Mar-2010	21-Apr-2010	28	19-Aug-2010	20-Aug-2010	FR	WAES1008USA01668	20-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	1597Y		Unknown	Unknown	
	VARCEL	GLAXOSMITHKLINE BIOLOGICALS	A70CB394A		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NJ02690		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Guillain-Barre syndrome, Loss of control of legs, Muscular weakness, Paraesthesia

Symptom Text: Information was obtained on request by the Company from the agency via a public case details form concerning a 12 year old female who on 24-MAR-2010 was vaccinated with a dose of GARDASIL (lot # NJ02690, batch # NJ47920). Suspect therapy on 24-MAR-2010 included RECOMBIVAX HB (thimerosal free, lot # 666571/1597Y, batch # N3850) and VARILRIX (lot # reported as A70CB394A). 4 weeks post vaccination, on approximately 21-APR-2010 the patient had pins and needles in her legs and was feeling weak and her legs kept collapsing from under her. The patient was admitted to hospital and diagnosed with Guillain-Barre syndrome. FI-LP and MRI were normal. Electrophysiology test was not conducted. The patient was treated with physiotherapy. At the time of the report, the outcome was unknown. The agency considered that the events were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, normal; diagnostic laboratory test, FI-LP normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **395812-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Jul-2010	20-Jul-2010	0	19-Aug-2010	20-Aug-2010	FR	WAES1008USA01765	20-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Syncope

Symptom Text: Information has been received from the health authorities, under the reference number ES-AGEMED-222589341, concerning a 14 year old female, with a medical history not reported, who on 20-JUL-2010 was vaccinated with a dose of GARDASIL via intramuscular. Concomitant therapy included FRENADOL. On 20-JUL-2010 the patient experienced loss of consciousness, dizziness and "lipotimia." Examination performed on 20-JUL-2010, showed a systolic pressure of 120 mmHg and a diastolic pressure of 60 mmHg, a heart rate of 76 bpm, an arterial oxygen saturation of 98% and a capillary glucose of 125 mg/dl. The patient completely recovered on the same day, on 20-JUL-2010, within a minutes. Case reported serious with other medically important condition as criteria. Other business partner numbers included: E2010-04793. Case is closed. No further information is available.

Other Meds: FRENADOL

Lab Data: blood glucose, 20Jul10, 125 mg/dl

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395821-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Aug-2010	18-Aug-2010	1	19-Aug-2010	19-Aug-2010	MN		19-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	13184	2	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	01592	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3246BA	5	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort, Injection site erythema

Symptom Text: REDNESS AT INJECTION SITE OF VARICELLA VACCINE, SIZE PALM OF HAND AND SOME DISCOMFORT

Other Meds:

Lab Data:

History: NO

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **395833-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-Aug-2009	Unknown		06-Aug-2010	31-Aug-2010	TX	201004039	03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2919AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U2933AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Initial case was received on 28 July 2010 from a healthcare professional. An 11 year old female received on 13 August 2009, a left deltoid intramuscular injection of ADACEL (reported lot number U29133 AA not valid for ADACEL, but is valid for MENACTRA), a right deltoid intramuscular injection of MENACTRA (lot number U2919AA) and a right deltoid intramuscular injection of GARDASIL (Merck lot number 1130X). The patient experienced numbness in both arms and legs since the vaccinations (onset date and time not specified). The patient had no pre-existing medical conditions, no concomitant medications and no known allergies. On 28 July 2010, the patient returned to the physician's office for an annual exam, reported the numbness and stated the symptoms continued. Document's held by sender: None. The following information was obtained through follow-up and/or provided by the government. 8/23/10 Received vaccine & PCP medical records for service dates 7/23/10 Assessment: Records reveal patient experienced numbness in extremities intermittently 3-4 x for 1 year starting 1-2 days after 1st vaccination in 8/09. Parent refused remainder of series. Exam WNL. Had been referred to Endocrine after abnormal TSH/T4.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 8/23/10 Received medical records w/LABS done 9/21/09: TSH 6.06(H), T4 0.89(L). MRI brain WNL.

History: The patient had no pre-existing medical conditions, no concomitant medications and no known allergies.

Prex Illness:

Prex Vax Illns:

Vaers Id: **395836-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Jul-2010	14-Jul-2010	1	06-Aug-2010	01-Sep-2010	CA	201003883	02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U34400AA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Hemiparesis, Injection site swelling, Pain, Swelling, Swelling face

Symptom Text: Initial case received from a physician on 14 July 2010. A 16-year-old female patient received a right arm injection of MENACTRA (lot number U34400AA) and a left arm injection of GARDASIL (Merck, lot not reported) on 13 July 2010. The patient had a history of ADHD (attention deficit/hyperactivity disorder) and depression, and 8 months prior to vaccination had suffered a head trauma with symptoms involving the right side. Concomitant medications included PRISTIQ, VYVANSE, and PAMELOR. On 14 July 2010, the morning after vaccination, the patient woke up with swelling of the right side including right-sided facial swelling and right arm swelling; right-sided weakness; and lower back pain. The patient noted that she had pain when trying to get up to walk, and that she "hurt all over". She was seen by her physician on 14 July 2010. Outcome was unknown at the time of the report.

Other Meds: PRISTIQ; VYVANSE; PAMELOR

Lab Data:

History: History of head trauma 8 months prior to vaccination with similar right sided-symptoms. Past medical history also included depression and ADHD; she had no known allergies.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395851-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Jun-2010	30-Jun-2010	2	19-Aug-2010	20-Aug-2010	LA	LA100801	23-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEP	MERCK & CO. INC.	1022Y	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	U2969AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3099A	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1332Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Joint range of motion decreased, Musculoskeletal pain, Pain in extremity, Tendonitis

Symptom Text: Pt returned for 2nd dose of HPV. Pt states has had pain in right shoulder and back of right arm since 1st HPV given in that arm. Pt states has difficulty raising right arm. Pt states symptoms began 2 days after shot was given. Pt denies injury. Pt states she has been taking ibuprofen for the pain. Pt went to see PMD Monday 8/2/2010. States was given a steroid and anti-inflammatory shot. Stated MD though pt had tendonitis or possibly torn ligament. Pt to revisit MD if symptoms continue past treatment.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **395858-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	M	10-Aug-2010	10-Aug-2010	0	19-Aug-2010	20-Aug-2010	AZ		24-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3337AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B055AB	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Intramuscular	
FLU(H1N1)	SANOFI PASTEUR	UP019AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Blood pressure decreased, Dizziness, Electrocardiogram normal, Grip strength decreased, Heart rate decreased, Syncope, Visual field defect

Symptom Text: 14 yr old male given 4 vaccines syncopal episode after administration. Assisted to prone position. B/P 138/70 pulse 56 then B/P 80/60. Hydrated, ate crackers, leaving with mom, felt dizzy weak, monitored in prone position c/o blurry peripheral vision, weak grips bilaterally. 911 called at 1725 VS WNL, BS 72, EKG normal. Mother states she would bring to ER but she did not. RN called to check on client next day and he was fine.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395862-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Aug-2010	17-Aug-2010	0	19-Aug-2010	23-Aug-2010	TX		26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0913Y	0	Left arm	Intramuscular	MNQ
	HPV4	MERCK & CO. INC.	1318Y	0	Right arm	Intramuscular	TDAP
	VARCEL	MERCK & CO. INC.	1704Y	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Feeling abnormal, Mydriasis, Syncope, Vomiting

Symptom Text: When client stood up, stated "I feel funny had her sit back down, when she sit down she then fainted-nurse lowered her to ground to lie with feet elevated. Client then woke with pupils dilated to 8. Oriented x 3. Pulse - 90 Resp 18 124/84 - After client rested for 15 min B/P 116/64 Pulse 74 Resp 16. Client states she did not eat breakfast or lunch today. Drank glass of water, 15 mins later 110/60 Resp 16 Pulse 70 strong and regular. Denies all s/s-states just feels tired. Client states had nausea on 8/16 at theme park, pupils not dilated-escorted to car per grandmother.

Other Meds: None

Lab Data: None 8/18-called GM-states yesterday she threw up then took nap for 3hrs- woke up feeling fine. No N/V/D-ate supper with no problems and woke up in the morning with no N/V/D No skin rash. Denies all problems. Denies headache. Will go to Doc

History: None

Prex Illness: States on 8/16 went to theme park got red hot and nausea

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395909-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2010	17-Aug-2010	5	19-Aug-2010	24-Aug-2010	WI		24-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3336AA	0	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045BA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0312Y	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral, Pain in extremity, Rash

Symptom Text: On 8/17 when pt. got up she had a rash looked like mosquito bites on a patch of her leg & arm. It spread by afternoon. 8/18 AM she was covered with the rash. She complained that her hands & feet hurt & edema hard to close her hand. Mom gave 3 doses of BENADRYL during the day. 8/19 improved but legs swollen - took BENADRYL & went to work.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395913-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	19-Aug-2010	19-Aug-2010	0	19-Aug-2010	24-Aug-2010	NY		26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1333Y		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives on (L) side of face.

Other Meds:

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **395970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-May-2010	18-Jun-2010	25	19-Aug-2010	24-Aug-2010	CA		26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hemiparesis, Paraesthesia

Symptom Text: Developed tingling & weakness (L) side of her body that lasted > 1 month. Started > 1 wk after IZ. No previous hx anxiety sx.

Other Meds:

Lab Data: Increased ESR 22 8/2/10

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **395997-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	06-Aug-2010	06-Aug-2010	0	20-Aug-2010	23-Aug-2010	LA	WAES1008USA00979	01-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1332Y	0	Right arm	Intramuscular	
	MEN	SANOFI PASTEUR	U3057AA		Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3051AA	5	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anxiety, Blood pressure decreased, Blood test, Bradycardia, Convulsion, Dehydration, Electrocardiogram, Fall, Gaze palsy, Injection site anaesthesia, Injection site discomfort, Muscle twitching, Nausea, Postictal state, Syncope, Tachycardia

Symptom Text: Information has been received from a consumer concerning her 13 year old son with no known drug reactions or allergies or pertinent medical history who on 06-AUG-2010, was intramuscularly vaccinated in the left arm with the first dose of GARDASIL, in the physician office. There was no concomitant medication. On 06-AUG-2010, following the administration of GARDASIL, the patient walked to the waiting room to sit with his mother. Within two or three minutes the patient fell to the ground seizing. The seizure activity lasted approximately three minutes. Emergency medical service was called because of sustained tachycardia and low blood pressure. It was noted that this resolved with a lengthening of the postictal phase of the seizure. The patient was then transported to the emergency room by his mother where blood work and electrocardiogram were performed (results not provided). The patient was then discharged to his home. According to the patient's mother he was currently very anxious. "Patient fell to the ground seizing", sustained tachycardia, low blood pressure and very anxious were considered to be disabling and life-threatening by the reporter. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 08/30/10. PCP visit and ER report for 08/06/10. Pt fell after receiving multiple immunizations, c/o RA numbness, twitching, Pt's eyes rolled back. Pt had discomfort at injections site. Pt also had nausea, brief bradycardia, decreased blood pressure. Tx: IVF. DX: syncope, dehydration. Pt improved and discharged in stable condition.

Other Meds: None

Lab Data: Unknown

History: None The following information was obtained through follow-up and/or provided by the government. PMH and allergies none.

Prex Illness:

Prex Vax Illns:

Vaers Id: **396011-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Aug-2010	11-Aug-2010	0	20-Aug-2010	24-Aug-2010	GA		24-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB382AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1378Y	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3359AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B047BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Chills, Headache, Lip swelling, Oropharyngeal pain, Pyrexia, Swelling face, Swollen tongue

Symptom Text: Vaccines given 8-11-10. Grandmother called 8-12-10 at 12:10 pm. Stating child last night had swollen face & lips and fever/chills, but temp NOT taken. Today, c/o headache, sore throat & swollen tongue. Denies fever/chills today. Denies difficulty breathing. Also c/o stomach ache. Decided not to go to ER or MD. Gave TYLENOL and sent back to school on 8/13/10. Advised she take her to her physician or ER for further evaluation. Advised the grandmother to call the Health Department to report results of her evaluation. August 13, 2010 - Client's grandmother did not call to report status. Called grandmother and she stated she did not take her to the doctor or the emergency room on August 12th but had given pt TYLENOL. She states that she was okay during the night and she sent her to school today and the school had not called her to come and get her so she thought she did okay.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396019-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	12-Aug-2010	12-Aug-2010	0	20-Aug-2010	24-Aug-2010	IA		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Decreased appetite, Pyrexia, Rash, Viral infection

Symptom Text: 8/13/10 mom calls Health Dept. & says child had fever of 101.9 orally. Giving ibuprofen every 4 hrs. w/some relief & then goes back up after 3-4 hours. Woke up today w/rash under his armpits extending down to his upper thighs. Denies itching. Loss of appetite. Mom calls physician after talking w/PHN. Has Dr. appt today & was told it is probably strep throat. 8/16/10 PC to mom - rash is gone. Still has fever & now has cough, saw Dr. 8/13/10 & no meds prescribed. Told is probably viral infection.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396026-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		20-Aug-2010	23-Aug-2010	FR	WAES1008USA01063	23-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from health authorities (reference case number PEI2010022529). This case was poorly documented. Case medically confirmed and was considered as serious by HA. An adolescent female patient had received a dose of GARDASIL (lot number not reported), on an unspecified date. Unspecified time later the patient was found to have multiple sclerosis (diagnosed by McDonald criteria). At the time of the report, the patient's outcome was not mentioned. HA coding: multiple sclerosis. Other business partner number included E2010-04811. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396027-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		20-Aug-2010	23-Aug-2010	FR	WAES1008USA01799	23-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Sudden death

Symptom Text: Information has been received from a consumer, as part of a marketing research program concerning a 14 year old female who on an unspecified date was vaccinated with the second dose of GARDASIL (Lot # unknown). The consumer reported that the patient who was a friend of her daughter died suddenly 2 weeks after receiving the second dose of GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396104-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	06-Aug-2010	06-Aug-2010	0	20-Aug-2010	25-Aug-2010	MT		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	SANOFI PASTEUR	NULL		Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Pallor

Symptom Text: BECAME PALE AND PASSED OUT AFTER HPV VACCINE # 1

Other Meds:

Lab Data: NONE

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **396109-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Aug-2010	20-Aug-2010	0	20-Aug-2010	25-Aug-2010	TX		25-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1207Y	1	Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049BA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3075AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1778Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dyskinesia, Hypotonia

Symptom Text: Rcvd Tdap, Varicella, MCV4 and HPV. After receiving the last dose (was HPV) - started to seize - lasted approximately 30 seconds of jerking and then went limp. Came to immediately and was alert and oriented.

Other Meds:

Lab Data: n/a

History: None but mother has epilepsy and her aunt has a history of epilepsy

Prex Illness: None

Prex Vax Illns:

Vaers Id: 396120-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	05-Feb-2010	15-Apr-2010	69	21-Aug-2010	24-Aug-2010	MI		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	SKBAHAVB302BA	1	Right arm	Intramuscular	HEPA
	HPV4	MERCK & CO. INC.	MS01060U	2	Left arm	Intramuscular	HPV4 TDAP

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Hodgkins disease, Lymphadenopathy

Symptom Text: Hodgkin's Lymphoma symptoms began in April 2010. Diagnosed August 6th, 2010. The following information was obtained through follow-up and/or provided by the government. 08/31/10. U/S of thyroid and neck on 07/19/10: multiple lymph nodes noted bilaterally in the neck.

Other Meds:

Lab Data: The following information was obtained through follow-up and/or provided by the government. 08/31/10. Labs and DX studies on 07/19/10: U/S of thyroid and neck: normal thyroid gland, but multiple lymph nodes noted bilaterally in the neck.

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: 396121-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	24-May-2009	Unknown		21-Aug-2010	23-Aug-2010	--		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Chest pain, Chills, Dyspnoea, Headache, Injection site swelling, Pain, Rash, Vision blurred

Symptom Text: Headaches, body aches, body chills, joint pain, chest pain, rash, trouble breathing, blurred vision, swollen spot at injection site.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396141-2** **Related reports:** 396141-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Aug-2010	14-Aug-2010	0	31-Aug-2010	31-Aug-2010	TX		01-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3337AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0093Z	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C33438AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Headache, Muscular weakness, Tremor

Symptom Text: Jerky reactions, headache, weakness in arms.

Other Meds: None reported

Lab Data: Neurological testing done. Results normal. Treated with medicine mother did not know name of. Had another reaction of tremors 08/30/2010 and family doctor called and Gabatentin prescribed. To see neurologist for further testing.

History: None reported

Prex Illness: None reported

Prex Vax Illns:

Vaers Id: 396167-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Aug-2010	18-Aug-2010	0	20-Aug-2010	24-Aug-2010	IL		27-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	0362Z	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0819Y	0	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U3074AA	0	Right arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B045CA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphasia, Dry skin, Gaze palsy, Injection site pain, Muscle rigidity, Mydriasis, Opisthotonus, Pallor, Screaming, Skin warm, Syncope

Symptom Text: After applying bandage to injection sites on right arm, patient began to state the last one hurt (HPV). Patient's speech stopped and pupils became dilated with eyes fixed upwardly. Patient became pale. Patient was assisted to floor where she became rigid and arched back. Patient let out a few blowing, pursed-lip breaths followed by a lash forward and scream. Immediately after the scream patient was talking and asking what had happened. Skin remained warm and dry, pale. Pupils returned to normal. Cool compresses were applied. Cool water was sipped. Blood pressure and pulse within normal limits. Entire syncopal episode lasted less than 5 minutes.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396208-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Aug-2010	19-Aug-2010	0	23-Aug-2010	25-Aug-2010	CT		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0565Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Within a minute after receiving HPV patient felt faint and then had a syncopal episode. Dr. was called into room. We placed her on exam table with her legs elevated. Within 5-10 seconds she regained consciousness, was able to talk. Vitals taken-states she feels better.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **396218-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Sep-2008	01-Sep-2008	0	23-Aug-2010	24-Aug-2010	FR	WAES1008PHL00085	24-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Fatigue, Pyrexia, Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning her 12 year old female daughter with a history of flu who in approximately September 2008, was vaccinated with first dose GARDASIL. Second and third dose were received on approximately December 2008 and approximately March 2009 respectively. Concomitant therapy included influenza virus vaccine (unspecified) and pneumococcal vaccine (unspecified). In September 2008, the patient initially complained of ankle joint pains. Upon inspection, ankles were not swollen. The ankle pains were described as "going on and off" as it appeared and disappeared spontaneously. Aside from ankle pains, the patient also complained of tiredness or fatigue. Subsequently, the patient experienced fever of unknown origin. After 2 weeks, the patient was hospitalized for a month and was diagnosed with lupus. The patient's lupus persisted and is now undergoing laboratory tests to check for complications on the heart and kidneys. The reporter felt that lupus was probably related to therapy with GARDASIL. It was noted that the patient did not have a family history of auto-immune disease and was other wise healthy prior to vaccination. This is one of two reports from the same source. Additional information is not expected.

Other Meds: Influenza virus vaccine (unspecified) 2009

Lab Data: Unknown

History: Flu

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396219-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Mar-2008	01-Sep-2008	184	23-Aug-2010	24-Aug-2010	FR	WAES1008PHL00088	24-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Muscular weakness

Symptom Text: Information has been received from a physician concerning her 12 year old female niece who in approximately March 2008, was vaccinated with third dose of GARDASIL. In September 2008, the patient experienced weakness in inner thigh and was hospitalized. Outcome of the event was unknown. At the time of the report, relationship of the weakness in the inner thigh with the therapy was unknown. It was noted that the patient was other wise healthy and had no prior related medical history. This is one of two reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396220-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Sep-2009	01-Sep-2009	0	23-Aug-2010	24-Aug-2010	US	WAES1008USA01851	30-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Anxiety, Aphasia, Arrhythmia, Asthenia, Cerebrovascular accident, Chest pain, Chorea, Convulsion, Fatigue, Headache, Immunoglobulin therapy, Lethargy, Lupus-like syndrome, Memory impairment, Myalgia, Nausea, Nervous system disorder, Pyrexia, Renal disorder, Syncope, Systemic lupus erythematosus, Tremor, Vasculitis cerebral

Symptom Text: Information has been received from a physician concerning her 15 year old daughter with no pertinent medical history or drug allergies who in September 2009, was vaccinated with a first dose of GARDASIL (lot # not reported). No concomitant medications were reported. It was reported that in September 2009, very soon after the injection of GARDASIL, the patient developed fatigue and nausea. When the patient was on leaving the physician's office she experienced syncope. The patient began having symptoms of high fever, headache and sore muscles. The patient was lethargic for months after she received GARDASIL. In June 2010 the patient had chest pain and went to the Emergency Room where she was diagnosed with anxiety. The EKG showed arrhythmias. The patient became weak and had to quit the Track Team at school. In June 2010 the patient was tired and lethargic and began to forget things. Approximately three weeks ago, in approximately August 2010, the patient developed a tremor in her left hand and she was unable to speak. The patient developed chronic seizures with chorea. On 08-AUG-2010 the patient was admitted to hospital. On 15-AUG-2010 the patient developed a stroke and was non verbal. The patient was diagnosed with drug induced systemic lupus erythematous with chorea. It was reported that there was central nervous system (CNS) involvement and the patient had vasculitis of the brain. The physician did not report what type of diagnostic testing the patient had received. The patient was being treated with ten different medications reported as follows: intravenous immune globulin (IVIG), antibiotics, anti hypertensive medications due to kidney involvement and high doses of IV prednisone. The physician stated that today, on 17-AUG-2010, the patient was to begin chemotherapy with IV cytotoxin for a duration of 24 hours. Currently, the patient had her voice back and was able to move all of her extremities except the left arm. As of 16-AUG-2010 the patient had not recovered from drug induced systemic lupus erythematosus w

Other Meds: Unknown

Lab Data: Electrocardiogram, 06/??/10, arrhythmias

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396225-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Aug-2010	14-Aug-2010	2	23-Aug-2010	25-Aug-2010	UT		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0436Z	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0644Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3440AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3049AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Red, hot to touch, swollen and tender right arm. Started on Keflex for cellulitis.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396232-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.5	F	19-Aug-2010	19-Aug-2010	0	23-Aug-2010	25-Aug-2010	NM		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	PNC13	WYETH PHARMACEUTICALS, INC	E52355	2	Right leg	Intramuscular	
	HPV4	MERCK & CO. INC.	0229X	0	Left leg	Intramuscular	
	DTAPIPVHIB	SANOFI PASTEUR	C3656AA	2	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Wrong vaccine administered. Order was for Hep b and Gardisil was given.

Other Meds:

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396253-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Aug-2010	16-Aug-2010	0	23-Aug-2010	25-Aug-2010	MN		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3473AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling

Symptom Text: Patient experienced between golf ball and tennis ball sized swelling at site of Meningococcal vaccine.

Other Meds: Trazadone 50 mg; CONCERTA 36mg; CELEXA 10mg

Lab Data:

History: Chronic otitis media; ADHD; Bipolar affective disorder

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396254-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Aug-2010	20-Aug-2010	0	23-Aug-2010	25-Aug-2010	GA		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0912Y	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1354Y	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Concussion, Convulsion, Dyskinesia, Immediate post-injection reaction, Syncope

Symptom Text: GARDASIL # 3 and Hepatitis A #2 given IM on left deltoid at 5:30 pm on 08-20-2010. 5 seconds after giving shots, patient had syncope (+) seizure like movement x 10 seconds- Patient with one jerking movement of upper extremity - patient was given the IM immunization seated on mother's lap - she hit the left side of the lap but did not have concussion/patient made to lie down pulse ox - monitoring (+) HR (+) BP - monitored - patient made to lie down and observed in office x one hour.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: Dizziness~HPV (no brand name)~2~13.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396255-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	Unknown	Unknown		23-Aug-2010	25-Aug-2010	TX		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB379BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Hyperhidrosis

Symptom Text: About 1 minute after receiving shots he leaned against wall and slid down to the floor face down. Nurse placed ammonia inhaler near his face and responded to his mother. He remained diaphoretic for several minutes. His pulse was regular 76.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396272-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-Aug-2010	20-Aug-2010	0	23-Aug-2010	25-Aug-2010	GA		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0565Z	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling cold, Flushing, Skin warm, Thirst, Throat tightness

Symptom Text: Flush skin, tightness in throat. Client received vaccine at approximately 11:25 am after checkout, returned to front counter at approximately 11:45 am and reported to the Office Manager that she was experiencing tightness in her throat. Office Manager came to the back to inform this nurse. This nurse returned to the front and brought the client to the back. The client was alert and oriented, reporting a tightness; upon swallowing. Upon assessment client throat appears normal; client was able to swallow actually asking for water. Skin was flush in appearance and very warm to touch. No respiratory distress noted. BP was 118/68 @ 11:50 am. RN was alerted to initiate protocol. Client received BENADRYL 50 mg IM at 12n, BP: 106/60. At 12:05 pm EMS was alerted due to client reporting no change in status. BP: 120/20. Client reports feeling "cold" and "very thirsty". At 12:10pm BP: 130/90 and client remains alert and oriented - attempting to call husband. Client in semi-fowler's position with cool cloth on neck cover with drapes for warmth. At 12:15 pm, BP: 120/94. At 12:20 pm EMS arrived and took over care of client. BP: 125/79, client reports no change in status since receiving BENADRYL 50 mg IM. Client departed on stretcher via ambulance to hospital at 12:25 pm. This nurse called client at 4:45 pm. Client answered cell phone and reported that she was doing well and went home with no other problems, about twenty minutes after receiving IM Epinephrine in Emergency Room.

Other Meds:

Lab Data: None

History: Previous allergic reactions unsure Abx (3) per client.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396285-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Aug-2010	17-Aug-2010	0	24-Aug-2010	25-Aug-2010	IN		30-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3281BA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3516AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Decreased appetite, Fatigue, Headache, Pyrexia

Symptom Text: Evening of 8/17/2010 fever, headache 8/18/2010-fever, headache, chest pain, fatigue decreased appetite.

Other Meds: TRI-SPRINTEC; AUGMENTIN; MOBIC

Lab Data: EKG

History: Human Papillomavirus vacc, qval preservative free

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396294-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Aug-2010	20-Aug-2010	0	24-Aug-2010	25-Aug-2010	MI		30-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1332Y	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3356AA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3333AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Pallor, Syncope, Tremor, Unresponsive to stimuli, Visual impairment

Symptom Text: Pt received TDAP, MENACTRA, HPV vaccines today. About 10 seconds later, she started to shake, eyes rolled into her head, her vision went black, and she collapsed onto the examining table. She was quickly positioned on her back with legs elevated. She turned pale. O2 = 100%, HR 87. She was responsive. Patient was observed for 15 min. and recovered fully. Upon discharge her O2 = 100%; HR 88; BP 112/68. She has no h/o syncopal episodes with imms.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396306-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Aug-2010	19-Aug-2010	1	24-Aug-2010	25-Aug-2010	PA		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0096Z	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash erythematous

Symptom Text: GARDASIL administered 8/18/10. On 8/19/10, developed diffuse red, raised bumps on injection arm. Itchy, about the size of mosquito bites.

Other Meds:

Lab Data: None indicated

History: Sulfa allergy

Prex Illness: None

Prex Vax Illns:

Vaers Id: 396311-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	10-Aug-2010	16-Aug-2010	6	24-Aug-2010	25-Aug-2010	IL		26-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1778Y	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3336AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061CA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1658Y	1	Left arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB379BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Rash macular

Symptom Text: Initially, rash on abdomen noticed. Today, generalized macular erythematous patches seen over the trunk and forearms, 2-3 cm in size, profuse over the abdomen.

Other Meds: None

Lab Data: CBC (Diff/PLT); CMP (with EGFR); allergy eval; childhood allergy (food & environmental) profile - results pending 8-18-10

History: None known

Prex Illness: None

Prex Vax Illns: Rash?~Vaccine not specified (no brand name)~UN~0.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396326-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Aug-2010	03-Aug-2010	0	24-Aug-2010	26-Aug-2010	OH		30-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0664Z	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Rash pruritic

Symptom Text: Began to break out in itchy rash approximately 3 hrs after GARDASIL #2. On PE, had large areas of erythema without scale scattered over upper extrem, (L) orbit, neck, trunk. No wheals noted. Rx: prednisone.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	20-Aug-2010	20-Aug-2010	0	24-Aug-2010	25-Aug-2010	IN		26-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049CA		Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1302Y		Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB427BA		Right arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB824CA		Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0664Z		Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3068AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Child was in to get vaccines, waited approx 10 minutes after receiving the vaccines and was walking out when he became light headed and lowered to the floor, did not lose consciousness, when asked if he had anything to eat or drink today he replied "No" Patient was given a juice box, dad kept saying, " he will be ok" Patient set with back up against a wall while drinking juice box, regained color and feeling better within five minutes. After watching for approx 5 more minutes, he walked to his car, where father was driving.

Other Meds:

Lab Data:

History: None reported

Prex Illness: None reported

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396364-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Aug-2010	23-Aug-2010	0	24-Aug-2010	25-Aug-2010	NC		25-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0664Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Patient had just had her blood drawn and then felt light headed and nauseated, felt like she was goint to faint. She was taken to an exam room to lie down.

Other Meds:

Lab Data: None

History: Anemia

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396377-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Aug-2010	24-Aug-2010	0	24-Aug-2010	26-Aug-2010	CA		31-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0249Y	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Dizziness, Headache, Micturition urgency

Symptom Text: Couldn't see after receiving HPV vaccine approximately 2 minutes after. Felt lightheaded. Felt like she had to go to the bathroom c/o headache.

Other Meds:

Lab Data:

History: None

Prex Illness: No illness

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396380-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Aug-2010	19-Aug-2010	1	24-Aug-2010	26-Aug-2010	FL		31-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U3360AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1778Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Aphagia, Dyspnoea, Gastroenteritis viral, Hypersensitivity, Pruritus, Rash, Vomiting

Symptom Text: Rash over arms, legs, body itching - slight SOB. Mom saw pharmacist -> BENADRYL given. Allergic reaction started next day after vaccines given. Child also used new soap and possibly this was the cause of the reaction. Child also c/o abdominal cramps. Unable to eat but able to drink fluids. Probable stomach virus. Vomited x 1 at home. When seen rash was resolving but still visible. No SOB noted. Mother instructed to continue BENADRYL PRN. Watch for SOB. Keep child hydrated. See MD or go to ER if symptoms worsen or if child unable to take fluids.

Other Meds:

Lab Data:

History: asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396395-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Aug-2010	21-Aug-2010	4	24-Aug-2010	26-Aug-2010	MI		30-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0672Y	0	Left leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Groin pain, Lymphadenopathy

Symptom Text: Patient received GARDASIL 8/17/2010. Limping and complaining of pain in groin area 8/22/10; noticed lump in groin area 8/23/2010. Diagnosed as swollen lymph node. Advised to call if symptoms worsen & to call when symptoms are resolved. Lymph node .5 cm in diameter.

Other Meds: YAZ; CELEXA; SEROQUEL

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396396-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Aug-2010	24-Aug-2010	1	24-Aug-2010	26-Aug-2010	OH		31-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3360AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U2936BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling, Oedema peripheral, Swelling face

Symptom Text: Swelling of face, fingers, feet & lips upon awaking. BENADRYL at home, went to E.R.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396415-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Aug-2010	21-Aug-2010	11	25-Aug-2010	27-Aug-2010	AZ		31-Aug-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U3337AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA	0	Left arm	Intramuscular	
MMR	MERCK & CO. INC.	1660Y		Unknown	Subcutaneously	
HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	
HEPA	MERCK & CO. INC.	0261Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Rash

Symptom Text: Mom reports that child has been feeling ill since vaccines. On 8/21/10 mom noted rash on trunk spread to face. Mom stated her sibling had same experience with MMR in past. We encouraged to stay home from school & see her physician for Dx. She will call MD.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: Rash~Measles + Mumps + Rubella (no brand name)~1~1.00~Sibling

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396419-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Aug-2009	14-Aug-2009	0	25-Aug-2010	27-Aug-2010	US		01-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Syncope

Symptom Text: My daughter fainted after the first GARDASIL shot and was extremely fatigue after the third GARDASIL shot.

Other Meds:

Lab Data:

History: She had no other preexisting conditions and is a healthy, active teenager.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: 396436-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Aug-2009	15-Sep-2009	41	25-Aug-2010	26-Aug-2010	--	WAES0911USA02384	26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0312Y	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Caesarean section, Chorioamnionitis, Drug exposure before pregnancy, Foetal heart rate disorder, Immunoglobulin therapy, Labour complication, Pyrexia

Symptom Text: Information has been received from a medical assistant for GARDASIL, a Pregnancy Registry product, concerning an 18 year old female patient with type O Rh(D) negative blood and a history of 1 pregnancy and 1 elective termination who on 05-AUG-2009 was vaccinated with the first dose of GARDASIL (lot# 662404/0312Y). Concomitant therapy included prenatal vitamins (unspecified). Subsequently, the patient became pregnant. Her LMP was 15-SEP-2009. On 11-NOV-2009, ultrasound done for viability and dates, result showed intrauterine pregnancy (IUP) seen approximately 13 weeks. The patient's estimated date of delivery was 19-MAY-2010 and the baby was normal. At the time of the report, the patient's outcome was unknown. Follow-up information has been received from a medical assistant who reported that on 09-DEC-2009 serum alpha-fetoprotein screening was performed for routine pregnancy test, with normal result. It was also reported that the patient's blood type is O negative. The patient also had one previous pregnancy which she electively terminated at 11 weeks gestation. At the time of the report, the patient's outcome was unknown. Follow-up information has been received which reported that the patient did not agree to participate in the Pregnancy Registry for GARDASIL. Follow up information has been received from the physician who reported that the patient was admitted to the hospital with the pre-operative diagnosis: Intrauterine pregnancy at: 40w 6d, chorioamnionitis, protracted labor, nonreassuring fetal heart rate tracing (NRFHT); Post-operative Diagnosis: status post delivery of VMI, normal pelvic anatomy, same. The patient was seen prior to surgery (Primary Low Transverse Cesarean Section). The risks, benefits, complications, treatment options, and expected outcomes were discussed with the patient. The patient concurred with the proposed plan, giving informed consent. The site of surgery properly noted/marked. A Time Out was held and the above information confirmed. While the patient was being prepped, the FHT were

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 11/11/09, normal, IUP seen approx 13 1/2 weeks; serum alpha-fetoprotein, 12/09/09, normal; hemoglobin, 05/26/10, 11.8; hematocrit, 05/26/10, 33.5

History: Termination of pregnancy - elective

Prex Illness: Pregnancy NOS (LMP = 9/15/2009); Rhesus antibodies negative

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396437-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	01-Jul-2010		25-Aug-2010	26-Aug-2010	TN	WAES1008USA02077	26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Carcinoma in situ, Cervical dysplasia, Loop electrosurgical excision procedure, Neoplasm malignant

Symptom Text: Information has been received from a physician concerning a 22 year old female patient who was vaccinated with three doses of GARDASIL in the physician's office in 2007. It was reported that the patient now had cancer. She visited the physician's practice within the last 3 week, in approximately July 2010, and was presented with cervical dysplasia, abnormal Pap smear, positive HR-HPV, biopsy came back as carcinoma in situ (CIS). She had the loop electrosurgical excision procedure (LEEP). At the time of the report, the patient's outcome was unknown. Upon internal review, carcinoma in situ (CIS) was determined to be an other important medical event. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, positive HR-HPV; biopsy, carcinoma in situ (CIS); Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396501-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	25-Aug-2010	25-Aug-2010	0	25-Aug-2010	27-Aug-2010	NY		01-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1378Y	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Vaccine positive rechallenge

Symptom Text: Pt and mom reported to RN that he had a previous episode of fainting on 6/22/10 after receiving GARDASIL and MENACTRA. Had pt sitting for GARDASIL #2. Fainted within 1 minute and came to within 1 minute. Kept at chair for 30 min & able to walk out & OK.

Other Meds: None

Lab Data:

History: Allergic to Amoxicillin

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396506-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	24-Aug-2010	24-Aug-2010	0	25-Aug-2010	27-Aug-2010	NJ		02-Sep-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061BA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3055AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	13184	0	Right arm	Intramuscular	
HEPA	MERCK & CO. INC.	04152	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling, Urticaria

Symptom Text: Developed urticaria, swelling of lips 6-8 hours after receiving vaccine. Denies wheezing or shortness of breath.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **396519-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Aug-2010	24-Aug-2010	0	26-Aug-2010	27-Aug-2010	MN		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	07862	2	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Dizziness, Headache, Nausea

Symptom Text: 4hr after dizzy -lightheaded- headache. Stomach nausea with temp.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396558-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Aug-2010	18-Aug-2010	0	26-Aug-2010	27-Aug-2010	CA		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Movement disorder, Pain

Symptom Text: Pt had numbness, couldn't move left arm, for a few hrs. Went to ER, but left before being seen. Next day pt doing fine, except for some pain. This was 2nd injection.

Other Meds: None

Lab Data: None

History: None known

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396574-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Jul-2010	27-Jul-2010	0	26-Aug-2010	27-Aug-2010	TX	WAES1008USA02980	27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	IPV	SANOFI PASTEUR	C3249AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0249Y	0	Unknown	Intramuscular	
	DTAP	SANOFI PASTEUR	C3249AA		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U3076AA		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Initial and following up information has been received from a physician and a medical assistant, for GARDASIL, a Pregnancy Registry product, concerning a 20 year old female patient with irregular periods, with a history of car accident (a few years back) and subsequently with an addiction to pain medications, who on 27-JUL-2010 was vaccinated IM with the first 0.5 ml GARDASIL (lot# 663453/0249Y). Concomitant vaccinations included DTAP-IPV (lot# C3249AA) and MENACTRA (lot# U3076AA). Concomitant therapy also included pain medications. On 27-JUL-2010, the patient was advised to see an OBGYN physician and was advised to see a Psychologist. On 27-JUL-2010, the patient had an abnormal pap smear. During the second week of August 2010, the patient called the physician's office and reported that on 30-JUL-2010 (three days after she had received the vaccinations) she had a miscarriage. The miscarriage was not confirmed by a physician. The patient stated that she had irregular periods and she was not sure that she had a miscarriage. The patient was advised to follow-up with her OBGYN physician. The M.A. did not know if the patient recovered. Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: cervical smear, 07/27/10, abnormal

History: Automobile accident

Prex Illness: Pregnancy NOS (LMP = Unknown); Drug dependence; Irregular periods

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396592-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	M	04-Aug-2010	05-Aug-2010	1	26-Aug-2010	26-Aug-2010	IN		26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0597Z	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB382AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Mom called to report that patient developed hives, welts all over torso. Pt was advised to call family doctor.

Other Meds:

Lab Data:

History: asthma

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396594-1** **Related reports:** 396594-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Aug-2010	24-Aug-2010	0	26-Aug-2010	26-Aug-2010	FL		26-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3433AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	U3035CA		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1409Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall

Symptom Text: AFTER RECEIVING VACCINES, MOM STILL IN LAB AND PATIENT STARTED TO WALK, FELL DIZZY AND FELL ON FLOOR.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396594-2** **Related reports:** 396594-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Aug-2010	24-Aug-2010	0	31-Aug-2010	02-Sep-2010	FL		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0565Z	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1409Y	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	U3035CA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U3433AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall

Symptom Text: After receiving vaccines, mom still in lab and patient started to walk, felt dizzy and fell on floor.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396615-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	26-Aug-2010	26-Aug-2010	0	26-Aug-2010	27-Aug-2010	ID		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0245Z	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	
	MMR	MERCK & CO. INC.	0071Z	1	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3448AA	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0161Z	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: 5 min afer vaccine administered pt c/o dizziness which lasted 40 minutes.

Other Meds:

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396626-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	20-Aug-2010	20-Aug-2010	0	26-Aug-2010	27-Aug-2010	TX	TX20100092PU	02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB379BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1318Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Heart rate normal, Hyperhidrosis

Symptom Text: ABOUT 1 MINUTE AFTER RECEIVING SHOTS HE LEANED AGAINST WALL AND SLID DOWN TO THE FLOOR FACE DOWN. NURSE PLACE AMMONIA INHALER NEAR HIS FACE AND HE RESPONDED TO HIS MOTHER. HE REMAINED DIAPHORETIC FOR SEVERAL MINUTES. HIS PULSE WAS REGULAR.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396636-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Aug-2010	25-Aug-2010	0	26-Aug-2010	27-Aug-2010	WA		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Pallor

Symptom Text: Lost color in her face, then lost consciousness and had went into seizure.

Other Meds:

Lab Data: CT Scan MRI Scan Total blood work

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **396637-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Aug-2010	17-Aug-2010	4	26-Aug-2010	27-Aug-2010	CA		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB417BA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0644Z	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B063BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chromaturia, Musculoskeletal stiffness, Rash

Symptom Text: Rash and stiffness in the hands. Started on prednisone. 4 days later stiffness was moving to the arms. Rash was improved. Lab work at this time all negative for lupus or arthritis. Several days later, she complained of stiffness of the legs.

Other Meds: None Had 5 prior doses of Dtap, last in 5/2001

Lab Data: Component 8/21/2010 Specimen source CLEAN Appearance, urine CLEAR Color, urine YELLOW MICROSCOPIC EXAM, URINE NOT IND CULTURE STATUS

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **396653-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
4.0	M	24-Aug-2010	24-Aug-2010	0	26-Aug-2010	27-Aug-2010	CA		27-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0597Z	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Asthenia, Dizziness, Feeling cold, Nervousness, Pain in extremity

Symptom Text: HPV given at 2:15 PM. Pt waited 15 mins. After vaccine in order to see if any reaction occurred. Pt was fine after the 15 mins. And left. At 4:00PM mother came back to office stating pt was feeling shaky and arm where vaccine was given was hurting. He was put in a room. And O2 sats and BP were observed. He was given Orapred 3os PO x 1 At 4:10 PM, Then given Benadryl 2 TSP at 4:26PM. At 4:26 PM. He was a little anxious and continued to have pain. At 4:15 he still had pain and felt weak/cold. At 5:34 He had less pain, but felt dizzy. He had a good BP. He was observed until 6:12 PM. He was sent to ER in order for observation to continue. He was given Morphine and oxygen in ER. He was released at 1:30AM.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **396655-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Jan-2010	27-Jul-2010	189	26-Aug-2010	27-Aug-2010	TX		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1480Y	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: LGSIL pap, HPV effects 1 year after GARDASIL vaccines referred to Gyn.

Other Meds:

Lab Data: Pending colpo/biopsies

History: PCN; anxiety

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396688-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		27-Aug-2010	30-Aug-2010	OH	WAES1008USA02977	30-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Epilepsy

Symptom Text: Information has been received from an immunization technician. She heard from a patient who heard from an occupational therapist who heard from another person that one patient with a history of seizure was vaccinated with the second dose of GARDASIL. Concomitant therapy included seizure medication. Subsequently the patient experienced seizure. It was unknown if the patient was hospitalized. It was reported that "the patient was diagnosed with epilepsy". Therapy with GARDASIL was discontinued. At the time of reporting, the outcome was unknown. It is unknown if the patient sought medical attention. Upon internal review, epilepsy was determined to be an other important medical event. This is one of several reports received from the same source. The Immunization Technician stated that she did not remember the patient's name or contact information who reported that she heard about a patient that was diagnosed with epilepsy after receiving GARDASIL. Attempts to verify the existence of an identifiable patient have been unsuccessful. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vaers Id: **396689-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		27-Aug-2010	30-Aug-2010	US	WAES1008USA02983	30-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Movement disorder

Symptom Text: Information has been received from a physician assistant concerning a female who was vaccinated with her second dose of GARDASIL (lot # not provided, dates of vaccination not available). On an unknown date, the patient experienced seizure like symptoms. Therapy with GARDASIL was discontinued due to the adverse event. It was unknown if the patient sought medical attention. At the time of the reporting, the patient's status was unknown. Upon internal review, seizure like symptoms was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396690-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		27-Aug-2010	30-Aug-2010	OH	WAES1008USA03152	30-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Epilepsy

Symptom Text: Information has been received from an immunization technician. She heard from a patient who heard from an occupational therapist who heard from another person that one patient was vaccinated with the second dose of GARDASIL. Subsequently the patient experienced seizure and was hospitalized. It was reported that "the patient was diagnosed with epilepsy". Therapy with GARDASIL was discontinued. At the time of reporting, the outcome was unknown. This is one of several reports received from the same source. The Immunization Technician stated that she did not remember the patient's name or contact information who reported that she heard about a patient that was diagnosed with epilepsy after receiving GARDASIL. Attempts to verify the existence of an identifiable patient have been unsuccessful. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396711-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Aug-2010	26-Aug-2010	1	27-Aug-2010	30-Aug-2010	TX		30-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0413Z	1	Left arm	Subcutaneously	
	MEN	SANOFI PASTEUR	U3021AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling, Injection site warmth

Symptom Text: PT'S SITE OF INJECTION BECAME RED, SWOLLEN, ITCHY, AND HOT TO TOUCH. SITE MEASURED ABOUT 60MM.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396712-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Aug-2010	26-Aug-2010	1	27-Aug-2010	30-Aug-2010	TX		30-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0413Z	1	Right arm	Subcutaneously	
	MEN	SANOFI PASTEUR	U3021AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1539Y	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: PT'S INJECTION SITE BECAME RED, SWOLLEN, AND PAINFUL. REDNESS MEASURED ABOUT 30MM.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396715-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Aug-2010	28-Aug-2010	1	28-Aug-2010	30-Aug-2010	MD		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0786Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort, Headache, Injection site haematoma, Medical device complication, Pain, Pyrexia

Symptom Text: Pt received third (and final) Gardasil vaccine at 16:00 on 08/27/2010 @ doctor's office. RN giving vaccine had to attempt administration twice - plunger in syringe jammed after needle inserted into pt's arm. Syringe removed from pt's arm, plunger unjammed and injection administered on second try. Pt woke at 07:30 on 08/28/2010 with headache, fever of 102.4 F, generalized aches throughout body, slight swelling and bruising at injection site. 200mg Ibuprofin administered at 08:00 which did not alleviate fever or discomfort. Add'l 200mg Ibuprofin administered @ 09:00. Fever lowered to 100.4 but headache and body aches were not alleviated. Pt put into cool bath at 13:45 and received 400mb Ibuprofin. Fever lowered to 99.4 after bath. Fever abated at 17:00 and headache and body aches are almost gone.

Other Meds:

Lab Data: None

History: Tree nut allergy

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396741-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Aug-2010	24-Aug-2010	0	27-Aug-2010	30-Aug-2010	WA		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB401BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1539Y	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B043BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Hyperventilation, Injection site pain, Sensory disturbance

Symptom Text: After injection child began crying hysterically and saying the shot was burning her arm and then started hyperventilating. She then stated she could feel the medicine shooting through her body and that her legs wouldn't work. Pt insisted on leaving and walked to the car on her own.

Other Meds: Novlog; Lantus

Lab Data:

History: Diabetes I

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396747-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	19-Aug-2010	21-Aug-2010	2	27-Aug-2010	30-Aug-2010	GA		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3487AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0787Z	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Redness, tenderness and swelling at the site of injection. Was given KEFLEX 500mg % po q 12 hours at hospital.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396761-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	M	25-Aug-2010	25-Aug-2010	0	30-Aug-2010	30-Aug-2010	MD		30-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Cheilitis, Lip swelling, Pruritus

Symptom Text: Lip swelling with rash. Lips itchy and burning.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **396789-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Mar-2010	23-Mar-2010	0	30-Aug-2010	30-Aug-2010	TX		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0819Y	4	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Movement disorder, Staring, Vomiting

Symptom Text: LVN witnessed "seizure like activity" within seconds of receiving vaccine. Lasted 20 seconds. No loss of bowel or bladder continence. Emesis x 1. Blank stare and fatigued after episode. Prior hx of syncope with previous vaccines/injections.

Other Meds:

Lab Data: EEG done inconclusive (not normal, but no definitive epileptic waveforms noted)

History: No

Prex Illness: No

Prex Vax Illns: syncope~HPV (Gardasil)~2~0.00~Patient

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396797-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	18-Aug-2010	21-Aug-2010	3	30-Aug-2010	02-Sep-2010	NY		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	029011	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0996Z	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling, Local swelling

Symptom Text: Local reaction with erythema and swelling, firmness, tender to palpation.

Other Meds:

Lab Data:

History: Allergic to PCN; Latex: Corn; Banana; Peanuts

Prex Illness: None

Prex Vax Illns:

Vaers Id: **396801-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Jul-2010	24-Jul-2010	1	30-Aug-2010	02-Sep-2010	GA		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	AC52B053DB	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	MSD0652X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Tremor

Symptom Text: States on "the following evening started having shaking all over and all of her limbs were shaking" - saw Dr. on Sat and was told it was a reaction to the vaccines but did not required treatment because it was a nervous response - recommended not to continue series of GARDASIL.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **396831-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Mar-2010	24-Mar-2010	0	30-Aug-2010	31-Aug-2010	FR	WAES1008USA01736	02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Left arm	Unknown	
	HEP	MERCK & CO. INC.	1597Y		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Asthenia, Headache, Hypoaesthesia, Injected limb mobility decreased, Injection site pain, Nausea, Sensory loss

Symptom Text: Information has been received from an agency concerning a 12 year old female patient who on 24-MAR-2010, was vaccinated with a dose of GARDASIL into her left arm and a dose of RECOMBIVAX HB (Lot # 666571/1597Y) into her right arm. The student left the clinic but returned within 15 minutes complaining of headache nausea, abdominal pain and a "dead arm". The patient was unable to fell of support her own arm when it was held out from her body. The patient was observed by the nurses and then was advised to see her general practitioner (GP) if the symptoms did not improve. On 24-MAR-2010, the doctor phones in to inform that the student had presented to see him with profound weakness, sensory loss and neuro-deficit in left arm. The patient was referred to a pediatrician. On 25-MAR-2010, the patient was seen by a neurologist for a nerve conduction test. On 29-MAR-2010 in phone contact with the patient's mother, she reported that the nerve conduction tests were normal. The patient was still not moving her left arm and needed assistance with everyday tasks. The patient was not attending school. ON 31-MAR-2010, a phone contact with the patient's mother indicated that the patient was referred to see a psychologist next week. The student attended school "yesterday", on 30-MAR-2010, but returned home at 11:30 AM because she was suffering from left shoulder pain from carrying around a "dead arm". The reporting agency considered that headache nausea, abdominal pain and a "dead arm", profound weakness, sensory loss and neuro-deficit in left arm were possibly related to therapy with GARDASIL. The reporting agency considered that headache nausea, abdominal pain and a "dead arm", profound weakness, sensory loss and neuro-deficit in left arm were other important medical events. Additional information is not expected.

Other Meds: Unknown

Lab Data: Neurological examination, 29?Mar10, normal; Neurological examination, 29?Mar10, nerve conduction studies: normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396833-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Nov-2007	Unknown		30-Aug-2010	31-Aug-2010	US	WAES1008USA03586	31-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from the mother of her 15 year old female daughter, who in November 2007 was vaccinated with GARDASIL and after receiving the first dose of GARDASIL, the patient experienced seizures and was diagnosed with "CMT". Upon internal review, seizures and was diagnosed with "CMT" was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396852-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	04-Aug-2010	25-Aug-2010	21	30-Aug-2010	31-Aug-2010	NY		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0597Z	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Mental status changes, Thinking abnormal

Symptom Text: Was called by outside institution. Pt is admitted for acute mental status change. Physician caring for Pt states she is very disorganized in her thinking. Pt prior was normal functioning. Pt is still hospitilized in psychiatric hospital x 5 days.

Other Meds: loratidine 10 mg daily

Lab Data:

History: allergic rhinitis. NKDA. muscle soreness noted in chart.

Prex Illness: myalgias and sore muscles noted. recent travel from Overseas noted also.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396888-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Aug-2010	26-Aug-2010	0	31-Aug-2010	31-Aug-2010	MN		31-Aug-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0367Z	1	Right arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B061CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1332Y	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3081AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope, Urinary incontinence

Symptom Text: As patient was walking out of the room, she fainted. Her mother caught her. She lost consciousness for less than 10 seconds. She lost control of her bladder. Clinic personnel provided appropriate comfort and first aid measures: had patient lie down, cold pack, reassurance, monitored for 30 minutes for further adverse responses.

Other Meds: unknown

Lab Data: None- n/a .

History: Fish allergy

Prex Illness: None Reported.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396909-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Aug-2010	18-Aug-2010	0	31-Aug-2010	02-Sep-2010	MN		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	NOVARTIS VACCINES AND DIAGNOSTICS	029011	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B040BA		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0280Z	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0075Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site warmth

Symptom Text: Seen 8/20. Increased redness (no induration), (+) warmth site of Varicella, 6.5 cm x 7 cm erythema (symptoms started that night).

Other Meds: FLONASE

Lab Data:

History: Speech therapy ongoing

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396910-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Aug-2010	23-Aug-2010	0	31-Aug-2010	02-Sep-2010	FL		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3473AA	0	Right arm	Unknown	
	HEPA	MERCK & CO. INC.	08512	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0664Z	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abasia, Fatigue, Nausea, Pallor, Syncope

Symptom Text: Over course of 90 minutes, pt. had 3 syncopal episodes and nausea. Unable to walk w/o having syncope. Very pale and tired.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396925-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Aug-2010	19-Aug-2010	2	31-Aug-2010	02-Sep-2010	CA		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1178Y	2	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U3060AA	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1559Y	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Redness and swollen 2 inches on (L) arm.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396942-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Aug-2010	21-Aug-2010	0	31-Aug-2010	02-Sep-2010	CA		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U307AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049AA	5	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0313	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Pallor

Symptom Text: Minor patient received 3 vaccinations on date and time noted below. About 10 minutes later, patient fell to the ground and appeared to have fainted per witnesses. She was immediately responsive following the fall, but appeared pale in the face and lips. She was laid flat on her back with her legs above her heart. Her color returned quickly to her face and she denied feeling dizzy. She was also assessed by paramedics who were called to the scene.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396953-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Jul-2010	27-Jul-2010	0	31-Aug-2010	02-Sep-2010	IN		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B040BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1539Y	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3355BA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB382AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Pallor

Symptom Text: Left clinic feeling fine, mother stated within a few minutes pt c/o feeling lightheaded, became pale and passed out mother drove back to clinic. Pt observed in clinic x 30 min, given juice and crackers and reclined. No further reactions noted in clinic.

Other Meds: None

Lab Data:

History: None noted

Prex Illness: None

Prex Vax Illns:

Vaers Id: **396976-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	08-Jun-2010	08-Jul-2010	30	31-Aug-2010	01-Sep-2010	US	WAES1008USA01868	01-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Haemorrhage

Symptom Text: Information has been received from a 26 year old female for GARDASIL a Pregnancy Registry product, who on 08-JUN-2010 was vaccinated with a first dose of GARDASIL (route and lot number unspecified). On 08-JUL-2010, the patient was vaccinated with a second dose of GARDASIL (route and lot number unspecified). The patient reported that on 06-JUL-2010, she found out she was pregnant. On 08-JUL-2010, the patient had a miscarriage. It was reported that since 11-AUG-2010, she had abnormal bleeding. The consumer stated that she had a period after her miscarriage but since GARDASIL was given it had caused her to have this abnormal bleeding. The patient also stated she had a miscarriage due to GARDASIL. The patient sought medical attention by visiting the hospital office. It was reported she would had an appointment with a physician on 17-AUG-2010. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **396977-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Feb-2010	04-Mar-2010	6	31-Aug-2010	01-Sep-2010	US	WAES1008USA03568	01-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Vaginitis bacterial

Symptom Text: Information has been received from a health professional for the Pregnancy Registry for GARDASIL, concerning a 18 year old female with no pertinent medical history and no previous pregnancies who on 24-FEB-2010 was vaccinated with a first dose of GARDASIL (route and lot# not reported). The patient's last menstrual period (LMP) was 10-JAN-2010 and her expected date of delivery was 14-OCT-2010. On 04-MAR-2010 to 11-MAR-2010, the patient was treated with metronidazole for bacterial vaginitis. On 12-MAR-2010, 8 weeks from LMP, the patient had an elective termination. At the time of the report, the patient's outcome was unknown. Upon internal review, elective termination was determined to be an other important medical event. Additional information has been requested.

Other Meds: metronidazole

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 1/10/2010)

Prex Vax Illns:

Vaers Id: **396978-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		31-Aug-2010	01-Sep-2010	US	WAES1008USA03584	01-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: This report was received from Research Group and was assigned manufacturer report number MD003. A 19 year old female patient approximately 2 years ago, in approximately 2008 was vaccinated with a dose of GARDASIL. Three or four days after receiving the vaccine, the patient experienced seizures and was hospitalized. The action taken regard GARDASIL and the outcome of the patient were not reported. The reporter felt that seizures was related to therapy with GARDASIL. This was originally reported by a family practitioner. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **397021-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	02-Aug-2010	28-Aug-2010	26	31-Aug-2010	02-Sep-2010	CA		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	ANTH	MICHIGAN DEPT PUB HLTH	FAV248		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1776Y		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: LMP: 20 Jul 10, vaccinated 02 Aug 10. Positive preg test 23 Aug 10. Miscarriage 28 Aug 20. Symptoms involving abdomen/pelvis NEC. DX: spontaneous abortion.

Other Meds:

Lab Data: 23 Aug: Pos HCG

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **397062-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	30-Aug-2010	31-Aug-2010	1	01-Sep-2010	01-Sep-2010	MO		01-Sep-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B063BA		Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3468AA		Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB417BA		Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0664Z		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: Left upper arm swollen and red, warm to touch.

Other Meds:

Lab Data:

History:

Prex Illness: no

Prex Vax Illns:

Vaers Id: **397085-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	08-Jan-2010	06-Aug-2010	210	01-Sep-2010	02-Sep-2010	MI		02-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0311Y	2	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Carcinoma in situ, Papilloma viral infection

Symptom Text: HPV (+) Type 16. (-) pap on 6/17/09. (+) pap on 8/6/10 "carcinoma in situ". 8/17 Colposcopy with biopsies. 9/16 Surgery Scheduled.

Other Meds:

Lab Data: attached

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **397178-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	25-Aug-2010	25-Aug-2010	0	02-Sep-2010	03-Sep-2010	GA		03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0664Z	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphasia, Cold sweat, Decreased appetite, Disturbance in attention, Dizziness, Hypotension, Nausea, Presyncope

Symptom Text: Severe vasovagal reaction (hypotension, clamminess, nausea), which lasted about 50 minutes. He then had approximately 36 hours of lightheadedness, unable concentrating, poor appetite, dysphasia. All symptoms resolved spontaneously.

Other Meds: None

Lab Data: O2 Sat 98%; CBC and EKG - normal

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **397182-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Aug-2010	26-Aug-2010	0	02-Sep-2010	03-Sep-2010	NJ		03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0337Z	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Pallor

Symptom Text: Pale, Diaphoretic in office.

Other Meds: None noted

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **397212-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Dec-2008	31-Dec-2008	0	02-Sep-2010	03-Sep-2010	LA	WAES0901USA00847	03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse through the pregnancy registry for HPV vaccine concerning a 17 year old female with attention deficit/hyperactivity disorder who on 31-DEC-2008 was vaccinated with a dose of GARDASIL (lot # 660616/0570X), 0.5 ml, intramuscular route. Concomitant therapy included CONCERTA and RITALIN. On 07-JAN-2009, the patient called the office to inform office that she was pregnant. No adverse effects were reported. The patient's LMP and EDD were not reported. Follow-up information was received on 27-AUG-2010 from a medical assistance who reported that the patient had a miscarriage. According to the medical assistance, the doctor said the miscarriage happened early on her pregnancy but she could not provide a specific date. When asked if there was a pathology report she said there was no indication in chart that any testing was performed. She added that the patient was fine afterwards. Upon internal review miscarriage was considered to be an other important medical event. Additional information is not expected.

Other Meds: CONCERTA; RITALIN

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vaers Id: **397213-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Sep-2010	03-Sep-2010	TX	WAES1008USA03608	03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Cholecystectomy, Gallbladder disorder

Symptom Text: Information has been received from a physician concerning a female patient who on unspecified date was vaccinated IM with 0.5ml of GARDASIL. The patient got terrible pain in upper quadrant above the gall bladder after receiving GARDASIL (Number of doses unspecified). Her mother took her to several gastroenterologists (names and locations unspecified). Quite a few lab diagnostics tests were performed, the results were not reported. "The patient was hospitalized and finally got her gall bladder removed."It was stated "there was a problem with her gall bladder". After the surgery, she was getting better. The adverse event was considered to be disabling and other important medical event by the reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **397214-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Feb-2010	26-Feb-2010	1	02-Sep-2010	03-Sep-2010	FR	WAES1008USA04243	03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1353X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphonia, Laryngoscopy, Vocal cord disorder

Symptom Text: Information has been received and case reported by Health Authority (case n. 122094) (local case n. IT363/10). Initial report received on 17-Aug-2010. Case medically confirmed. A 15 year old female with no previous medical history was vaccinated on 25-Feb-2010 at 03:30 PM, with the first dose of GARDASIL (LOT# 1353X, batch # NL31800, site of administration not reported) via intramuscular route. On 26-FEB-2010 she experienced aphonia related to laryngoscopy for bilateral vocal cord hypotonia with oval shaped glottis without signs of inflammation and without increase in fever. Visit to ENT and phonetician. Anti-inflammatory treatment. Outcome was not reported. Upon internal review, aphonia was considered to be an other important medical event. Other business partner numbers included: E2010-04911. No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **397222-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Aug-2010	10-Aug-2010	0	02-Sep-2010	03-Sep-2010	PR	PR1024	03-Sep-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1778Y	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3359AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B063AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	04682	0	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness, Muscle contractions involuntary

Symptom Text: AFTER VACCINE ADMINISTRATION THE PATIENT RESTED FOR 15 MINUTES IN A CHAIR. AFTERWARD SHE STOOD UP AND SUDDENLY FELL DOWN (BACKWARD) AND HIT HER HEAD. SHE WAS UNCONSCIOUS AND HAD CONTRACTIONS IN THE EXTREMITIES.

Other Meds:

Lab Data: HEAD X-RAYS WERE NEGATIVE HAD MEDICAL EVALUATION WITH NO SIGNIFICANT FINDINGS.

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **397224-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	01-Sep-2010	01-Sep-2010	0	02-Sep-2010	03-Sep-2010	IN		03-Sep-2010

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0664Z	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U3068AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B049BA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1302Y	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness, Syncope

Symptom Text: The child had a syncopal event within 5 minutes after being vaccinated; fell to floor and hit forehead on the floor. Child regained consciousness within 10 seconds. Staff laid the child on the couch. Child alert and oriented to person, place, and time immediately. Staff had child lie on couch for approximately 10 minutes and then sit at side of couch for approximately 5 more minutes. The family stated that he had not eaten and he was given juice and crackers. The mother decided to keep the child home from school to observe. Mother advised to call her physician if child started to feel increasingly worse, nauseous, dizzy, etc. Family left clinic approximately 20 minutes after incident with instructions to monitor child on walk to car.

Other Meds:

Lab Data:

History:

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 30-MAR-10 - 07-SEP-10 All comb. w/AND

Vaers Id: **397226-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Sep-2010	01-Sep-2010	0	02-Sep-2010	03-Sep-2010	TX		03-Sep-2010

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Eye swelling

Symptom Text: Swelling of patient's left eye. Difficulty breathing.

Other Meds:

Lab Data:

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Total Non Serious	**789**	**81%**
Total Serious Non Fatal	**167**	**17%**
Total Death:	**13**	**1%**
Total All Reports:	**969**	