VAERS Line List Report

Vax Type: HPV4 Status Date: 01-JAN-11 - 30-APR-11 All comb. w/AND

Vaers Id: **381305-3 (D)** ***Related reports*** 381305-1; 381305-2

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	10-Mar-2011	14-Mar-2011	US	201001159	14-Mar-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2324AA	0	Left arm	Intramuscular	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Bacterial infection, Death, Headache, Joint sprain, Meningitis, Meningococcal infection, Nausea, Petechiae, Vomiting

Symptom Text: Initial report received on 19 February 2010 from a health care professional. A 16 year old female patient with an unknown medical history tested positive for Neisseria Meningitidis 2 years, 7 months, 18 days (963 days) after she received a first dose of MENACTRA (lot number U2324AA) on 26 June 2007 (route and site were unknown). The patient was seen by a physician on 12 February 2010 after an emergency room visit for a sprained ankle after playing in the snow. On 13 February 2010 at 10:30 AM, the patient was found dead in her home. On 14 February 2010 the patient had a real-time PCR assay of the brain for detection of Neisseria meningitidis performed which detected Neisseria Meningitidis serogroup C DNA. A spinal tap was done during an autopsy which revealed gram negative rods Meningitis Type C DNA. The physician stated that the patient did not have any symptoms of meningitis. No further information was provided. Follow-up information received on 08 November 2010 from another manufacture (manufacturer report number WAES 1010USA03110) who had received the report from a FDA line listing (VAERS identification number 381305). The following is verbatim from the other manufactures report. "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 26-JUN-2007 was vaccinated with GARDASIL IM with the first dose. Second suspect therapy included MENACTRA (lot number U2324AA) IM into the left arm with the first dose. Concomitant therapy possibly included lithium. In the evening of 12-FEB-2010, the patient experienced headache, nausea, vomiting. In the morning of 13-FEB-2010 the patient was found dead. Autopsy performed 14-FEB-2010 - meningococcal disease determined to be cause of death, Gram negative diplococci observed on brain stem area, petechial rash observed by pathologist. Neisseria meningitidis serogroup C confirmed by polymerase chain reaction (PCR) on brain stem tissue on 14-FEB-2010. The listing indicated that one or more of the events resulted in death was considered to be immediately life-threatening. No further information is available. The original reporting source was not provided. The VAERS identification number is 381305." It is noted the subject's correct age is 16 years old as calculated from birth date to onset of events. The age of 13 years old as reported in the other manufacturer's report was the subject's age at the time of the vaccination. List of Documents held by Sender: lab results.

Other Meds: Lithium

Lab Data: Autopsy spinal tap revealed gram negative rods, meningococcal type C. 14/Feb/2010: Neisseria Meningitidis PCR and Neisseria Meningitidis Serogroup PCR of the brain : Neisseria Meningitidis serogroup C DNA detected.

History: No illness at the time of vaccination. Medical history was unknown.

Prex Illness:

Prex Vax Illns:

Vaers Id: **417137-1 (D)** ***Related reports*** 417137-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	04-Jan-2011	02-Feb-2011	29	18-Feb-2011	21-Feb-2011	TN	TN1101	26-May-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0096Z	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3432AA	0	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Cardiac arrest, Death, Endotracheal intubation, Fall, Haematemesis, Joint stiffness, Loss of consciousness, Peripheral coldness, Presyncope, Pulse absent, Resuscitation, Viral infection, Vomiting

Symptom Text: Patient deceased within 30 days of vaccine administration. The following information was obtained through follow-up and/or provided by the government. 5/11/11 ER records received. Service date 2/2/11 Diagnosis: Cardiac Arrest. Patient and family members had recent viral illness and vomiting. Had taken nonsteroidals. Near syncope at clinic, vomited blood and fell down. EMS found unconscious and pulseless. Arrived at ER in cardiac arrest/asystole. Hands cool, ankle stiffness. CPR/ALS continued, intubation. Chest compressions, femoral central venous catheter placed for ongoing resuscitation. Patient expired. 5/25/11 Received Autopsy Report which states COD as: group A streptococcal toxic shock syndrome. Report also indicates pt had 3 day hx of sore throat, nausea, vomiting & diarrhea. Findings at autopsy included: DIC; (+) throat, lung, csf & blood cultures; pulmonary hemorrhage; pleural effusions; dehydration; obesity; superficial abrasion of left thigh. Original focus of infection unclear but strep throat could not be ruled out since post-mortem c/s (+) & illness began w/sore throat.

Other Meds: NORINYL

Lab Data: The following information was obtained through follow-up and/or provided by the government. 5/11/11 Labs and Diagnostics: Glucose 150 mg/dL (H). CBC - RDW 14.3% (H) Platelets 80 K/uL (L) Segs 7% (L) Lymph 67% (H) Mono 21% (H) Myelo 3% (H) Segs# 0.6 K/uL (L) Lymph# 5.4 KuL (H) Mono# 1.7 K/uL (H) NRBC 2 /100WBC (H), Burr Cells mild, Schistocytes Mild, Many Bacteria Noted - Compatible with Septicemia. PT >90.0 sec (H), INR >9.80 (H) PTT >200 sec (H). ECG - Abnormal. Chest X-ray - Abnormal. 5/25/11 Autopsy report labs: throat c/s (+), lung c/s (+), csf c/s (+), blood c/s (+) all with heavy growth group A streptococcus

History: Hay fever; Animal fur

Prex Illness: none

Prex Vax Illns:

Vaers Id: **419174-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	F	04-Oct-2010	07-Oct-2010	3	21-Mar-2011	22-Mar-2011	FR	WAES1103USA00922	22-Mar-2011

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 Cardiac disorder, Condition aggravated, Cough, Death, Haemoptysis, Malaise, Renal disorder

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with longstanding health problems (according to mother) since childhood who on 04-OCT-2010 was vaccinated IM with a second dose of GARDASIL (Lot# not reported). In September 2010, the patient experienced cough and was sick. On 07-OCT-2010, the patient experienced cough and haemoptysis. On 30-OCT-2010, the patient was diagnosed with kidney "problem" and heart "problem". The patient was admitted to hospital. The patient's mother cannot recall treatment or hospital ID number and had not kept files. On 03-NOV-2010, the patient died. The cause of death was not reported. Cough, sickness, haemoptysis, kidney "problem" and heart "problem" were considered to be immediately life-threatening by the reporter.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-JAN-11 - 30-APR-11 All comb. w/AND

Vaers Id: **419237-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		22-Mar-2011	23-Mar-2011	US	WAES1103USA02079	23-Mar-2011

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 Unevaluable event

Symptom Text: Information has been received from a website concerning thousands of other young girls who on unspecified dates were vaccinated with a dose of GARDASIL (lot # not reported). The girls have experienced "life-destroying side effects" or death following their HPV vaccines. Life-destroying side effects were considered to be immediately life-threatening. This is one of two reports 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 Status Date: 01-JAN-11 - 30-APR-11 All comb. w/AND

Vaers Id: **421582-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	M	01-Nov-2010	01-Nov-2010	0	22-Apr-2011	25-Apr-2011	US	WAES1104USA02226	25-Apr-2011

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 Death, Sudden cardiac death

Symptom Text: Information has been received from a nurse practitioner concerning a patient's nephew, a 17 year old male consumer who she "thought" was vaccinated with a dose of GARDASIL (lot number not provided) in November 2010. The nurse practitioner stated that two weeks after the patient received the dose of GARDASIL, approximately November 2010 (also reported as "two weeks ago" on approximately 01-APR-2011), the patient died of sudden cardiac death on the lacrosse field. Unspecified medical treatment was given. It was unspecified if any lab diagnostic test were performed. The cause of death was sudden cardiac death. Sudden cardiac death was considered to be immediately life-threatening and disabling by the reporting nurse practitioner. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **293388-2 (D)** ***Related reports*** 293388-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	13-Jun-2007	06-Oct-2007	115	30-Aug-2011	31-Aug-2011	US	WAES0711USA00552	31-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	MEN	UNKNOWN MANUFACTURER	U2049AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0389U	1	Right arm	Unknown	

Seriousness: DIED, HOSPITALIZED, SERIOUS

MedDRA PT Brain death, Brain herniation, Chills, Death, Encephalitis, Headache, Malaise, Meningitis, Meningococcal infection, Neck pain, Pyrexia

Symptom Text: Information has been received via line listing from the FDA under the Freedom of Information Act from a health care professional on 10-OCT-2007. Additional information was received from a newspaper article concerning a 18 year old female with no medical history and was unknown if the patient was ill at the time of vaccination who on 10-MAY-2007 was vaccinated with GARDASIL (lot # 657736/0389U) in the right arm. On an unspecified date concomitant therapy included meningococcal ACYW conj vaccine (name, manufacturer, and lot # U2048AA) in the left arm. The patient who was a college freshman travelled on 05-OCT-2007 to visit her family for the weekend. The patient reportedly felt "slightly ill" upon her arrival and subsequently took an aspirin and went to bed awakening at 1:30 PM the following afternoon "appearing refreshed". The patient became feverish again that night and woke at 1:00 AM the morning of 07-OCT-2007 with chills and a severe headache complaining that "my headache is about to explode". The patient was taken to a local hospital, where a brain computed axial tomography (CAT) scan was performed and the brain revealed meningococcal disease in her brain and brain stem. The patient was immediately transferred to another hospital and died the evening of 07-OCT-2007 due to complications of meningitis. The health department noted that the "lab tests have not yet confirmed the strain of meningitis" but that it was "likely the type not prevented by the vaccination". The listing indicated that pyrexia, meningitis, malaise, headache and chills required hospitalization and resulted in death. Follow-up information was received from the FDA under the Freedom of Information Act. The lot numbers and site of administration was updated. Additional information was obtained from an agency who reported that an 18 year old female patient received a meningococcal ACYW conj vaccine (name, manufacturer, and lot number not reported). On an unspecified date, the patient who was a college freshman, travelled on 05-OCT-2007, to visit her family for the weekend. She reportedly felt "slightly ill" upon her arrival and subsequently took an aspirin and went to bed, awakening at 1:30pm. The following afternoon "appearing refreshed". She became feverish again that night, and awoke at 1:00am the morning of 07-OCT-2007 with chills and a severe headache, complaining, that "my head was about to explode". She was taken to a local hospital, where a CAT scan of the brain revealed meningococcal disease in her brain and brain stem. She was immediately transferred to another hospital and died that evening of 07-OCT-2007 due to complication of meningitis. The health department noted that "lab test had not yet confirmed the strain of meningitis" but that is was "likely the type not prevented by the vaccination". Past medical history and concomitant medication were unknown. It was not known if the patient was ill at the time of vaccination. On [Due to memory limitations, the remainder of this text could not be compared.] 18-OCT-2007, the patient name received from FDA. On 18-OCT-2007, it was received death certificate from funeral home which stated cause of death as brain death due to cerebral herniation and meningoencephalitis. On 26-OCT-2010, received vaccination record from the primary care physician which indicated that the patient received GARDASIL (lot# not reported) and MENACTRA on 10-MAY-2007. VAERS database updated with the same vaccination record indicated that the patient also received the second dose of GARDASIL (lot# 657868/0523U, left arm). On 27-NOV-2007, reviewed hospital medical records which reveal patient experienced headache, fever and neck pain for 1 day. A preliminary lot check investigation was performed. To date our investigation has found that the lot # 657868/0523U and the lot # 657736/0389U are conformed to quality release parameters and the manufacturing was typical of a lot of GARDASIL. Additional information will be provided upo

Other Meds:

Lab Data: head computed axial, 10/07/07, (BRAIN CT SCAN) showed meningococcal disease; WBC count, 10/07/07, 14.9; neutrophil count, 10/07/07, 67.2; absolute lymphocyte, 10/07/07, 6.4; serum creatinine, 10/07/07, 1.2; serum alanine, 10/07/07, 27; CSF white cell count, 10/07/07, 4455; red blood cell count,

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **417137-2 (D)** ***Related reports*** 417137-1

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	04-Jan-2011	Unknown		02-May-2011	03-May-2011	US	WAES1104USA01865	08-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0096Z	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U3432AA	0	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Death

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 allergy to animal fur and a history of hay fever on 04-JAN-2011 was vaccinated IM with a second dose of GARDASIL (lot # 666595/0096Z) into right arm and was vaccinated IM with a first dose of MENACTRA (lot # U3432AA) into left arm. Concomitant therapy included NORINYL. It was reported that patient deceased within 30 days of vaccine administration, (date not reported). The original reporting source was not provided. The VAERS ID # is 417137. A standard lot check investigation has been finalized. All in-process quality checks for the lot number in question (666595/0096Z) 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: NORINYL

Lab Data: Unknown

History:

Prex Illness: Hay fever; allergy to animal

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424378-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
12.0	F	Unknown	Unknown		01-Jun-2011	03-Jun-2011	FR	WAES1105USA03486	03-Jun-2011

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: Case reported by a consumer and retrieved from a website by a healthcare professional (specialist) who transmitted to agency on 18-May-2011. This case was not medically confirmed. The consumer published an open letter about vaccination on the website, a citizen's association. This open letter was addressed to an Agency. A 12-year-old female patient was vaccinated with a dose of GARDASIL (lot and batch number not reported) on a recent date in. It was reported that the patient deceased 2 days after the vaccination. Medical history: It was reported that the patient was in excellent condition before the vaccination. Following to the reporter, the GP had told the parents that the vaccine was very safe but that, unfortunately, the patient had reacted to it. Until now, no other source confirmed the case. The healthcare professional (specialist) wrote to the consumer for more information. Other business partner included E2011-03076. 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 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **424381-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	15-Feb-2011	03-Apr-2011	47	01-Jun-2011	03-Jun-2011	FR	WAES1105USA03118	03-Jun-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1016Z	2	Unknown	Unknown	

Seriousness: DIED, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain, Death

Symptom Text: Information has been received from a physician as part of the GARDASIL Access Program concerning a female who entered a HPV vaccine pilot project. On 15-FEB-2011 was vaccinated with 3rd dose of GARDASIL (lot # 666987/1016Z). The patient was admitted to hospital with abdominal pain and distension on 03-APR-2011. The patient died on hospital on 07-APR-2011. The cause of death was abdominal pain and abdominal distension. The reporting physician felt that abdominal pain (grade 5) and abdominal distension (grade 5) were not related to GARDASIL. Abdominal pain (grade 5) and abdominal distension (grade 5) were considered to be immediately life-threatening. A lot check has been initiated. 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 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425513-1 (D)** ***Related reports*** 425513-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
18.0	F	26-Apr-2011	28-Apr-2011	2	16-Jun-2011	17-Jun-2011	ID		05-Jul-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	VARCEL	MERCK & CO. INC.	1492Z	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0886Z	0	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Asphyxia, Completed suicide, Death, Suicidal ideation

Symptom Text: None known -suicidal ideation denied at visit 4/26 - known chronic depression she elected to stop her medications when she turned 18. Committed suicide 04/28/11. Hung herself. The following information was obtained through follow-up and/or provided by the government. 6/27/11 Autopsy report received. COD attributed to Asphyxia due to hanging by ligature with 1) Ligature mark of neck. 2) Hemorrhage in L Cricothyroid muscle and at base of L thyroid cornu. 3) Fractures of R&L sides of hyoid bone. Report reveals that pt made statement of intent to hurt/kill themselves. Pt was found by police hanging from deck.

Other Meds: ORTHO CYCLEN

Lab Data: None

History:

Prex Illness: (1) Depression/chronic; (2) ADHD; (3) acne severe

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425598-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		17-Jun-2011	20-Jun-2011	US	WAES1106USA01652	20-Jun-2011

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

Seriousness: DIED, SERIOUS

MedDRA PT Death, Thrombosis

Symptom Text: A consumer reported that he/she read an internet concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (lot # , dose and route not reported). On an unspecified date, the patient died of "clot blood" eight hours after vaccination. 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 Line List Report

Vax Type: HPV4 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **425680-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Jun-2007	01-Jun-2007	0	20-Jun-2011	21-Jun-2011	US	WAES1106USA01650	21-Jun-2011

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, Loss of consciousness, Resuscitation

Symptom Text: A consumer reported that he/she obtained the information from internet concerning a 17 years old woman who in June 2007 was vaccinated the first dose of GARDASIL. In the afternoon of the same day, in June 2007, the patient was found unconscious (without signs of life) by her mother. The doctor from the emergency crew attempted resuscitation, but without success. The cause of death was unspecified. 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 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429007-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		08-Aug-2011	09-Aug-2011	US	WAES1108USA00348	09-Aug-2011

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 concerning her daughter who was vaccinated with GARDASIL. The consumer reported that he had nothing to live for because GARDASIL killed his daughter. It was unknown if the patient sought medical attention. 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 Status Date: 01-MAY-11 - 15-SEP-11 All comb. w/AND

Vaers Id: **429121-1 (O)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		09-Aug-2011	10-Aug-2011	US	WAES1107USA04018B	16-Aug-2011

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 Death, Drug exposure via breast milk

Symptom Text: Information has been received from a Doctor of science who authored an article published in journal. The author reported that a breast-feeding mother on unspecified date was vaccinated with GARDASIL and that shortly following the vaccination her baby died. The author stated that both mother and child were completely healthy prior to the vaccination. The mother's experience has been captured in WAES 1107USA04018. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **381305-2 (D)** ***Related reports*** 381305-1; 381305-3

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*
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2324AA	0	Left arm	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 Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412282-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		09-Dec-2010	10-Dec-2010	US	WAES1011USA03821	10-Dec-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 Unevaluable event

Symptom Text: Information has been received from a nurse practitioner, who mentioned a magazine's article concerning 70 young female patients who, on an unspecified date, were vaccinated with a dose of GARDASIL (lot #, expire date and route not reported), 0.5 ml. On an unspecified date the patients died from "neurological causes" after being given GARDASIL. "Neurological disorders" were considered to be immediately life-threatening and disabling by the nurse practitioner. Additional information has been requested. This is one of two reports from the same source. Attempts are being made to verify the existence of identifiable patients. This is one of two reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412906-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
17.0	F	01-Sep-2007	01-Sep-2007	0	15-Dec-2010	16-Dec-2010	US	WAES1012USA01993	16-Dec-2010

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 Adverse event, Arthralgia, Death, Fatigue, Headache, Myalgia, Stress

Symptom Text: Information has been received from a consumer who was received the information from the internet. The information in the internet was received by a consumer concerning her 17 year old daughter who in July 2007 was vaccinated with the first dose of GARDASIL (Lot not reported). There was no adverse events. In September 2007, the patient was vaccinated with the second dose of GARDASIL (Lot not reported). Following vaccination, the patient experienced joints and muscle pain, fatigue, strong headaches etc. The physician related the symptoms to mental stress and prescribed TYLENOL for the treatment of headaches. The reporter indicated that no one thought that the symptoms were related to therapy with GARDASIL. On 20-FEB-2008, the patient was vaccinated with the third dose of GARDASIL (Lot not reported). On 22-FEB-2010 the reporter found the patient dead on the bathroom floor. An autopsy did not find the cause of death. The reporter felt that the patient had died because of GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **413697-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Dec-2010	30-Dec-2010	US	WAES1012USA02761	30-Dec-2010

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

Seriousness: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with the second dose of GARDASIL (lot number not provided). The physician was visiting his dentist and was talking to the dental hygienist about GARDASIL. The dental hygienist said she had a friend whose daughter died after getting the second dose of GARDASIL. It was unknown if the patient sought medical attention. The reporter considered death to be disabling and life-threatening. The health care professional contacted during telephone follow-up could not supply the following information: patient name, date of birth, dates of vaccination, lot number, date of event, hospital name (if applicable), and healthcare provider name and contact information. 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 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **397437-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		03-Sep-2010	07-Sep-2010	NY	WAES1008USA04132	07-Sep-2010

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

Seriousness: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician that he heard from a parent of one of his patients who also heard from elsewhere concerning a female who was vaccinated with a 0.5ml dose of GARDASIL, IM. "Some time passed, then she died". The cause of death was not reported. The patient received unspecified medical attention. Died was considered to be disabling and immediately life-threatening. 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 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **398755-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
0.2	F	01-Sep-2010	01-Sep-2010	0	17-Sep-2010	20-Sep-2010	FR	WAES1009USA00625B	20-Sep-2010

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

Seriousness: DIED, SERIOUS

MedDRA PT Death, Drug exposure via breast milk, General physical health deterioration

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL, concerning a female who on 01-SEP-2010 was vaccinated with the first dose of GARDASIL (lot number not reported) intramuscularly while breastfed her baby was 40 day old (WAES 1009USA00625), it was reported that the mother's and baby's health were good (well controlled). On 02-SEP-2010, in the morning, the baby's condition was still good but in the afternoon the condition suddenly drop. The family immediately took the baby to hospital and it did not help since the baby died shortly after that. The cause of death was not reported, it was also reported as "not recovered from death". No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **403759-1 (D)** ***Related reports*** 403759-2

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
10.0	M	09-Sep-2010	17-Sep-2010	8	18-Oct-2010	19-Oct-2010	NJ		15-Aug-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1778Y		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	UA3058AA		Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3476AA		Left arm	Unknown	
	HEPA	MERCK & CO. INC.	0568Z		Right arm	Unknown	

Seriousness: DIED, ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Asthenia, Autopsy, Death, Malaise, Myocarditis

Symptom Text: Mother called me on 9-17-10 afternoon that her son is sick and feeling very weak. I recommended the mother to take him to nearest ER as the patient was about 50 miles away and mother took him to ER where he was transferred to another hospital. The following information was obtained through follow-up and/or provided by the government. 8/12/11 Autopsy report received. COD is Myocarditis. Manner of Death: Natural.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405381-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	U	Unknown	Unknown		26-Oct-2010	27-Oct-2010	FR	WAES1010PHL00038	27-Oct-2010

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

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician concerning a friend of her patient who was vaccinated with GARDASIL. Subsequently the patient's friend died. The cause of death was not reported. The patient decided to discontinue vaccination due to the incident. No further information is available. Attempts to confirm an identifiable patient had been unsuccessful.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **405821-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
15.0	M	30-Aug-2010	27-Sep-2010	28	28-Oct-2010	29-Oct-2010	NJ	WAES1010USA02704	17-Feb-2011

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	1333Y	0	Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Bronchial hyperreactivity, Cardiomegaly, Congenital cardiovascular anomaly, Death, Left ventricular hypertrophy, Pulmonary oedema

Symptom Text: Information has been received from a physician concerning a 15 year old male with asthma and "cardiac history" (unspecified) who on 30-AUG-2010 was vaccinated with GARDASIL (Lot number 665607/1333Y). Concomitant therapy included LIPITOR. On 27-SEP-2010 the patient died while playing hockey. The physician reported "awaiting autopsy results". At the time of report no further information was available. The reporter considered death to be life-threatening. A lot check has been initiated. Additional information has been requested. The following information was obtained through follow-up and/or provided by the government. 11/16/10 Received Autopsy report which states COD as: congenital subaortic membrane w/reactive airway disease as contributing factor. Manner of death: natural. Gross autopsy findings included: mod to marked pulmonary edema; cardiomegaly; LV hypertrophy; subaortic membrane.

Other Meds: LIPITOR

Lab Data: Unknown

History:

Prex Illness: Cardiac disorder; Asthma

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **405998-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
Unknown	F	Unknown	Unknown		29-Oct-2010	01-Nov-2010	US	WAES1010USA02400	01-Nov-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 Unevaluable event

Symptom Text: Information has been received from a physician who reported in a magazine article regarding Cervical Cancer and in the article physician stated that "GARDASIL has caused 70 young healthy girls to die right after receiving the vaccine due to neurological problems. CERVARIX is covering three other HPV strains and it has been proven." No further AE information filed. There was no specific patient information, physician information, or date of death for the 70 patients in the article. Neurological problems considered to be immediately life-threatening. 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 Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **406289-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
19.0	F	06-Aug-2010	19-Aug-2010	13	02-Nov-2010	02-Nov-2010	MI		18-Nov-2010

VAX Detail:	*Type*	*Manufacturer*	*Lot*	*Prev Doses*	*Site*	*Route*	*Other Vaccine*
	HPV4	MERCK & CO. INC.	0640Z	1	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Condition aggravated, Contusion, Grand mal convulsion, Pulmonary congestion, Pulmonary oedema, Sudden death

Symptom Text: Patient had her first Gardasil shot on 02/15/2010. On 02/19/2010, she had a Grand Mal seizure. She had her 2nd shot on 08/06/2010. She died on 08/19/2010. Medical Examiner listed cause of death as Sudden unexpected death associated with Seizure Disorder. The following information was obtained through follow-up and/or provided by the government. 11/16/10 Received Autopsy report which states COD as: sudden unexpected death associated with generalized seizure disorder. Manner of death: natural. Autopsy findings: history as below; pulmonary congestion & edema; minor scalp contusion.

Other Meds:

Lab Data:

History: Autism The following information was obtained through follow-up and/or provided by the government. 11/16/10 Received Autopsy report which states PMH: autism; atraumatic generalized seizure disorder w/abnormal EEG. 11/16/10 Received PCP medical records for service date 2/15/10. Pt w/acute right otitis media when received HPV #1. Tx w/oral antibiotics.

Prex Illness:

Prex Vax Illns: seizure~HPV (Gardasil)~1~19.42~Patient

VAERS Line List Report

Vax Type: HPV4 Status Date: 01-SEP-10 - 31-DEC-10 All comb. w/AND

Vaers Id: **412247-1 (D)**

Age	*Gender*	*Vaccine Date*	*Onset Date*	*Days*	*Received Date*	*Status Date*	*State*	*Mfr Report Id*	*Last Edit Date*
14.0	F	01-Aug-2007	Unknown		08-Dec-2010	09-Dec-2010	US	WAES1012USA00781	09-Dec-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 Adverse event, Convulsion, Death, Fatigue, Hypoaesthesia, Initial insomnia, Mood altered, Ovarian cyst, Paraesthesia, Respiratory arrest, Syncope, Urinary tract infection

Symptom Text: Information has been received from a physician via a consumer who provided the physician with a link to a forum. The information was received from the patient's mother, from the link, concerning her healthy 14 year old daughter who in August 2007, January 2008, and June 2008, was vaccinated with a first, second and third dose of GARDASIL (lot # not provided). It was reported that the patient experienced several symptoms including numbness and tingling in her fingers and toes, fatigue, a really hard time falling asleep, urinary tract infections, ovarian cyst, moody, trouble getting out of bed and seizures. The patient had had upwards of 150 seizures following her third shot in June 2008. During her seizures she stopped breathing for periods of 30 to 40 seconds. The patient was diagnosed with Neurocardiogenic syndrome and seizures. It was reported that the patient died due to ovarian cyst. The reporter felt that the patient's symptoms were related to vaccination with GARDASIL. Upon internal review, the seizures were considered to be other important medical events "seizures" as an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: