	VAERS ID	Age	Onset days	Cause of Death
1	275428	12	6	Myocarditis
2	275438	19	14	Blood clots
3	275990	Unknown	3 hours	Blood clot
4	278865	15	58	Influenza, sepsis
5	279592	Unknown	14	Blood clot
6	280163	11	3	Anaphylactic shock
7	282372	17	0	Unknown
8	282747	Unknown	Unknown	Unknown
9	287888	22	2	Unknown
10	291804	17	50	Unknown
11	293388	18	115	Meningitis
12	297528	12	21	Unknown
13	299377	19	16	Unknown
14	300066	26	0	Blood clot
15	300741	18	1	Unknown
16	305606	17	Unknown	Unknown
17	309233	12	56	Arrhythmia
18	310262	20	14	Unknown
19	314524	17	Unknown	Unknown
20	316983	17	15	Idiopathic seizures
21	317695	42	2	Unknown
22	317757	15	2	Cardiomyopathy, arrhythmia
23	318244	20	Unknown	Pulmonary embolism
24	318491	Unknown	Unknown	Allergic reaction to Gardasil
25	319533	21	17	Cardiac Arrest, unknown causes
26	319810	14	14	Unknown
27	320559	Unknown	Unknown	??? (unverified)
28	320909	21	Unknown	Unknown
29	320910	Unknown	4	Unknown
30	321405	Unknown	Unknown	Unknown
31	321696	16	3	Seizures, cause unknown
32	322250	22	Unknown	Unknown
33	323430	20	263	Unclassified neurologic process
34	324002	15	15	Massive pulmonary embolus
35	325063	17	11	Myocarditis
36	334611	19	12	Unknown
37	335270	18	86	Unknown
38	337242	20	Unknown	Unknown
39	337797	18	240	Unknown
40	338452	15	71	Unknown
41	338561	20	5	Unknown
42	339771	13	181	Unknown, cardiac arrest
43	341030	14	Unknown	Unknown
44	343612	23	25	Unknown
45	343777	11	Unknown	Unknown
46	344385	16	Unknown	Unknown
47	345435	21	Unknown	Unknown

Vaers Id: 275428-2 (D) Related reports: 275428-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Mar-2007	07-Mar-2007	6	12-Jun-2007	13-Jun-2007	--	WAES0705USA05008	13-Jun-2007

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0943R	1	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0263U	0	Left arm	Intramuscular	
HEPA	MERCK & CO. INC.	1280F	1	Right arm	Intramuscular	

Seriousness: DIED, ER VISIT, SERIOUS

MedDRA PT Death, Myocarditis, Ventricular tachycardia

Symptom Text: Information has been received on request from the FDA under the Freedom of Information Act concerning a 12 year old female with a history of aortic and mitral valve insufficiency (unknown etiology) who on 01-MAR-2007 was vaccinated IM into the left arm with a first dose of Gardasil (lot # 655849/0263U). Concomitant suspect therapy included a second dose of Varivax (lot # 652082/0943R) SC into the right arm and a second dose of Vaqta (inactive) (lot # 656017/1280F) IM into the right arm. On 07-MAR-2007 the patient presented to the ED with ventricular tachycardia and died. Preliminary autopsy finding was myocarditis. The original reporting source was not provided. A standard lot check investigation was performed (for Gardasil, Varivax and Vaqta). 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. No further information is available. This report was filed with the FDA. The VAERS number is 275428.

Other Meds: Unknown

Lab Data: Unknown

History: Aortic valve insufficiency; Mitral insufficiency

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 275438-2 (D) Related reports: 275438-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Mar-2007	26-Mar-2007	14	12-Jun-2007	13-Jun-2007	--	WAES0705USA05011	07-Feb-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0263U	0	Left arm	Intramuscular	

Seriousness: DIED, ER VISIT, SERIOUS

MedDRA PT Circulatory collapse, Coronary artery thrombosis, Pulmonary embolism, Sudden cardiac death, Thrombosis

Symptom Text: Information has been received on request from the FDA under the Freedom of Information Act concerning a 19 year old female with no history who on 12-MAR-2007 was vaccinated IM into the left arm with a first dose of Gardasil (lot #655849/0263U). There was no adverse reaction reported. Subsequently on 26-MAR-2007 the patient collapsed and died secondary to emboli. An autopsy was done and on the death certificate the following is documented "sudden cardiac death and pulmonary embolism." An echocardiogram revealed a very enlarged right ventricle and small left ventricle as well as large blood clots within both the right atrium and right ventricle. Coronary artery thrombosis and thrombosis were also reported. The original reporting source was not provided. 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 agency and was released. No further information is available. this report was filed with the FDA. The VAERS number is 275438.

Other Meds: Unknown

Lab Data: echocardiography 03/26/07 - very enlarged right ventricle and small left ventricle as well as large blood clots (see narrative)

History: none

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 275990-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-Apr-2007	12-Apr-2007	--	WAES0704USA00721	13-Apr-2007

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, Thrombosis

Symptom Text: Information has been received from a physician's assistant (PA), via a company representative, concerning a female patient who was vaccinated (date unspecified) with a dose of Gardasil the PA reported that "the patient died of a blood clot 3 hours after getting the Gardasil vaccine." The PA clarified that the patient was not vaccinated at her office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 278865-2 (D) Related reports: 278865-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Jan-2007	01-Mar-2007	58	31-Oct-2007	01-Nov-2007	--	WAES0707USA00772	01-Nov-2007

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

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

MedDRA PT: Acute respiratory distress syndrome, Carpal tunnel syndrome, Chest pain, Cough, Death, Diarrhoea, Intensive care, Intubation, Mechanical ventilation, Migraine, Multi-organ failure, Myalgia, Nasal congestion, Nausea, Oxygen supplementation, Petechiae, Pharyngolaryngeal pain, Pneumonia, Pneumonia staphylococcal, Pyrexia, Respiratory failure, Rhinorrhoea, Scoliosis, Sepsis, Staphylococcal infection, Vomiting

Symptom Text: Information has been received from the U.S. Centers for Disease Control and Prevention via a professional presentation at the Global Advisory Committee on Vaccine Safety, World Health Organization on 12-JUN-2007 and 13-Jun-2007 and a line listing obtained on request by the Company from the FDA under the Freedom of Information Act concerning a 15 year old (also reported as a 14 year old) female with a history of migraines and a history of hernia repair. Family history: younger sister also with strep negative sore throat and a letter from school that group A strep infections were present. on 02-JAN-2007, the patient was vaccinated with a first dose of Gardasil DTaP (manufacturer unspecified). On 01-MAR-2007, the patient developed a fever, sore throat, cough, and myalgia. On 02-MAR-2007, the patient was vaccinated with a second dose of Gardasil (lot # 654885/1424F) IM in her left arm. Concomitant therapy included topiramate (TOPAMAX). On 01-JUN-2007, the Death Certificate was received from the epidemiologist which revealed cause of death (COD) as multiorgan failure and influenza B viral sepsis with contributing cause of staphylococcal secondary infection. Medical records included with the death certificate indicated the patient was transferred to a higher level of care on 06-MAR-2007, was intubated and in pediatric intensive care unit (PICU) with pneumonia and acute respiratory distress syndrome (ARDS). Reportedly the patient had been in good health until 01-MAR-2007 when she developed sore throat, nasal congestion, rhinorrhea and a low grade fever. The patient continued to worsen and developed myalgias, chest pain and nonproductive cough with higher fever. She was seen by the primary care physician (PCP) on 05-MAR-2007 and rapid strep was negative. The diagnosis was probable influenza. She was sent home and developed nausea, vomiting, and diarrhea as well as petechial rash over her abdomen. She was taken to the outlying emergency room on 06-MAR-2007, and was found to be in respiratory failure. She was intubated and

Other Meds: Topamax

Lab Data: diagnostic microbiology - endotracheal culture: positive for MRSA; lymphatic structure - lymph node culture: negative; viral culture - influenza B isolated; urine culture - negative; rapid Streptococcus 03/05/07 - negative; nasal culture -

History: Migraine; Hernia repair

Prex Illness: Scoliosis; Carpal tunnel syndrome

Prex Vax Illns:

Vaers Id: 279592-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-May-2007	25-May-2007	--	WAES0705USA01964	25-May-2007

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

Seriousness: DIED, ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death, Thrombosis

Symptom Text: Information has been received from a licensed visiting nurse via a nurse practitioner. The nurse practitioner was told by a friend that a female patient was vaccinated with Gardasil and two weeks alter developed a blood clot. Subsequently the patient died. The cause of death was from the blood clot. The reporting licensed visiting nurse considered the blood clot to be immediately life-threatening and disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 280163-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-May-2007	04-May-2007	3	01-Jun-2007	04-Jun-2007	--	WAES0705USA04839	04-Jun-2007

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

Seriousness: DIED, ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Anaphylactic reaction, Cardiac arrest, Death

Symptom Text: Information has been received from a nurse practitioner who heard from an emergency room (ER) nurse that an 11 year old female was vaccinated "within in the past month" in approximately May 2007 with a first dose of Gardasil. Subsequently, 3 days after vaccination the patient presented to an ER. She experienced cardiac arrest, required lung bypass (ECMO) and "may not have expired." It was also reported by the same nurse that the physician from the hospital said that "the death was due to an anaphylactic reaction to Gardasil." The anaphylactic reaction and cardiac arrest were considered to be life threatening by the reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 282372-1 (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-2007	21-Jun-2007	FR	WAES0706USA02451	21-Jun-2007

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

Seriousness: DIED, SERIOUS

MedDRA PT: Autopsy, Loss of consciousness, Resuscitation, Sudden death

Symptom Text: Information has been received from a gynecologist who was informed of the case from another gynecologist concerning a 17 year old female who in June 2007 (week 23), was vaccinated with a first dose of Gardasil (lot number, injection site and route not reported). During the evening of the same day, the patient was found unconscious (lifeless) by the mother. Resuscitation was performed by the emergency physician but was unsuccessful. The patient subsequently died. The cause of death was sudden death. It was noted that the patient had a dental surgery the day before she was vaccinated. An autopsy was done. The results were not known. Other business partner numbers include E2007-03769. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Dental operation

Prex Illness:

Prex Vax Illns:

Vaers Id: 282747-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		25-Jun-2007	26-Jun-2007	--	WAES0706USA02351	26-Jun-2007

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 who attended a conference that mentioned two patients who were vaccinated with Gardasil. Subsequently the patients died. The cause of death not reported. 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 Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 287888-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	21-May-2007	23-May-2007	2	13-Aug-2007	14-Aug-2007	--	WAES0708USA00407	14-Aug-2007

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U		Unknown	Intramuscular	

Seriousness: DIED, ER VISIT, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female patient with no pertinent medical history or drug allergies who on 21-MAY-2007, was vaccinated IM with a 0.5ml dose of Gardasil (Lot# 657736/0389U). Concomitant therapy included hormonal contraceptives (unspecified) ("MERCET"). On 23-MAY-2007, the patient died suddenly. The cause of death was unknown. Unspecified medical attention was sought. Laboratory diagnostic studies included an autopsy which showed no findings. No product quality complaint was involved. The reporter stated that Gardasil did not cause the patient's death. Additional information is not expected.

Other Meds: hormonal contraceptives

Lab Data: autopsy - no findings

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 291804-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Jul-2007	01-Sep-2007	50	02-Oct-2007	03-Oct-2007	OH	WAES0709USA04400	29-Oct-2007

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1427F	1	Left arm	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT: Blood glucose increased, Death, Diabetic ketoacidosis, Pulse absent, Resuscitation, Unresponsive to stimuli, Vomiting

Symptom Text: Information has been received from a physician concerning a female who on an unknown date was vaccinated with the first dose of Gardasil (yeast, unknown lot number) and in July 2007, was vaccinated with the second dose of Gardasil. In September 2007, the patient died. No further details or symptoms were known regarding the patient's death. The physician mentioned that an autopsy would be done however, had not received the results yet. The reporting physician felt that the patient's death was not related to therapy with Gardasil. Additional information has been requested. 10/11/2007 Patient demographics provided by CDC. 10/15/07 Received vax record from pcp. VAERS database updated w/same. 10/15/07 Received pcp & hospital medical records from CDC which reveal patient experienced vomiting with elevated blood sugars who became unresponsive & pulseless. CPR started & taken to ER on 9/19/07. Resuscitation was unsuccessful & patient pronounced 9/19/07. 10/26/07 Reviewed autopsy report which reveals COD as diabetic ketoacidosis & manner of death as natural. Patient had been found by parent unresponsive at home. History of severe diabetes mellitus. Vitreous glucose 667 (H).

Other Meds: Unknown

Lab Data: Unknown Vitreous glucose 667 (H).

History: Unknown PMH: IDDM, uncontrolled. Smoker. Right buttock abscess 8/31/07. Anemia. Father w/diabetes. ALLERGIES: PCN, cipro, ultram (hives).

Prex Illness: IDDM, uncontrolled. Smoker. anemia.

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 293388-1 (D)

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	17-Oct-2007	18-Oct-2007	NY	200703414	11-Apr-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0389U	1	Right arm	Unknown	HPV4 MNQ

Seriousness: DIED, SERIOUS

MedDRA PT: Back pain, Brain death, Brain herniation, Brain oedema, Chills, Death, Encephalitis, Headache, Intubation, Lumbar puncture, Malaise, Meningitis meningococcal, Mydriasis, Nausea, Neck pain, Pallor, Photophobia, Posturing, Pupil fixed, Pyrexia

Symptom Text: This case was received from a health care professional on 10 October 2007. Additional information was received from a newspaper article. An 18-year-old female patient received a meningococcal vaccine (name, manufacturer, and lot number not reported) on an unspecified date. The patient, who was a college freshman, travelled on 05 October 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 October 2007 with chills and a severe headache, complaining that "my head is 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 October 2007 due to complications of meningitis. The health department noted that "lab tests have not yet confirmed the strain of meningitis" but that it was "likely the type not prevented by the vaccination". Past medical history and concomitant medications were unknown: it was not known if the patient was ill at the time of vaccination. 10/18/07 Patient name received from FDA. 10/18/07 Received death certificate from funeral home which states COD as brain death due to cerebral herniation and meningoencephalitis. 10/26/07 Received vax record from pcp which indicates patient received HPV & Menactra on 5/10/2007. VAERS database updated w/same. Vax record indicates patient also received 2nd dose of HPV 6/13/2007, Lot # 0523U, left arm. 11/27/07 Reviewed hospital medical records which reveal patient experienced HA, fever & neck pain x 1 day. Had come home from college 10/5 & developed chills next day. Seen in outlying ER where LP showed high pressure, grossly purulent CSF growing meningococcus. Intubated & IV antibiotics started & transferred to higher level of care. Neurosurgery & ID consults don

Other Meds:

Lab Data: 07/Oct/2007: Brain CT showed meningococcal disease ER LABS: CT scan & CXR WNL. WBC 14.9 (H), Neutros 87.2 (H), lymphs 6.4 (L). Creatinine 1.2 (H), ALT 27 (L). CSF WBC 4455 (H), RBC 171 (H), neutros 100% (H), glucose 29 (L), protein 371

History: Medical history and concomitant medications not reported; it was unknown if the patient was ill at time of vaccination.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 297528-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Sep-2007	06-Oct-2007	21	23-Nov-2007	26-Nov-2007	--	WAES0711USA02619	26-Nov-2007

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 Death

Symptom Text: Information has been received from a physician's assistant concerning a 12 year old female with no reported medical history who on approximately 15-SEP-2007 was vaccinated with Gardasil. It was noted that this was not where the vaccine was administered, rather they were the patient's family physician. On 06-OCT-2007 the patient died in her sleep. No further information was provided. No lot number was given. 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 All comb. w/AND

Vaers Id: 299377-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-Sep-2007	05-Oct-2007	16	12-Dec-2007	13-Dec-2007	FR	WAES0712USA01347	13-Dec-2007

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1475F	0	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Bronchitis, Death, Diarrhoea, Photophobia

Symptom Text: Information has been received from a gynecologist concerning a 19 year old female with no previous medical history reported, who on 19-SEP-2007 was vaccinated (route and site not reported) with the 1st dose of Gardasil (Batch# NF37120, lot#1475F). On the morning of 12-OCT-2007, the patient was found dead in her bed. One week prior to death the female suffered from diarrhea, treatment without antibiotics. The patient also developed light sensitivity. The evening before the patient died she was out with a girlfriend until 3:00 am in the morning. The reporting physician excluded any drug misuse, as she knew the female as a sportive young woman. Contraception was stopped 3 months before vaccination. No reason for the death was detected in autopsy. The only finding in the autopsy was mild bronchitis and mucus. The reporting physician excluded any connection between vaccination and death. Other business partners numbers include E2007-08849(0). Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 300066-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	12-Nov-2007	Unknown		17-Dec-2007	18-Dec-2007	TX	WAES0712USA02658	06-Mar-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0106U	1	Unknown	Unknown	HPV4

Seriousness: DIED, SERIOUS

MedDRA PT Death, Deep vein thrombosis, Obesity, Pulmonary embolism

Symptom Text: Information has been received from a physician concerning a large female who received one dose of Gardasil. Subsequently, the patient was found dead in her truck from a blood clot that traveled from her legs to her lungs. The cause of death was reported to be a blood clot. Additional information has been requested. 3/5/08 Autopsy states COD as pulmonary thromboembolus w/deep vein thrombosis of right leg & obesity as contributing factor.

Other Meds: Unknown

Lab Data: Unknown

History: Asthma, morbid obesity, smoker, occasional ETOH. OCP unknown

Prex Illness: Obesity

Prex Vax Illns:

Vaers Id: 300741-2 (D) Related reports: 300741-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-May-2007	23-May-2007	1	21-Dec-2007	26-Dec-2007	FR	DEPEIPEI2007006990	26-Dec-2007

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

Seriousness: DIED, SERIOUS

MedDRA PT Brain oedema, Haemorrhage, Hypoxia, Intracranial pressure increased, Loss of consciousness, Pulmonary oedema, Resuscitation, Sudden death

Symptom Text: Case narrative including clinical course, therapeutic measures, outcome and additional relevant information: Case initially received on 12-Jun-07. It was reported by a sales representative who was informed by a gynecologist (who himself had heard of the case from another gynecologist) that an 18-year-old female patient was vaccinated with the first dose of Gardasil (lot # and injection route and site not reported) on an unspecified date beginning June 2007 (week 23). In the evening of the same day she was found unconscious (or liveless) by the mother. Resuscitation was performed by the emergency doctor but was unsuccessful, i.e. the patient finally died. To be noted is an anamnesis of dental surgery. Follow-up 10.10.2007: results of autopsy. History: this female patient collapsed from total health status at home. After 3 hours of reanimation the patient was declared dead. In the recent history the patient had a dental surgery about two to three weeks ago. First vaccination with Gardasil 27.03.2007, second vaccination 1 day before the exitus (22.05.2007). Both times the patient had not felt bad and had not reported of any side-effects. Cause of death: not definitely clear, results of macroscopic examination of the heart could be a hint for a myocarditis (flaccid muscle with different colored spots - fleckig-scheckige Zeichnung). For clarification whether the patient died of myocarditis a histological examination was done. Result of histological examination: suspected diagnosis of myocarditis could not be supported. This patient did not have a myocarditis. Concluding results of the autopsy: the cause of death of this patient remain totally unclear. The following reasons for death of this patient can be excluded sepsis or any inflammatory reason e.g. due to the dental surgery, or anaphylactic reaction following the Gardasil vaccination. The results of a toxicological examination are pending. Possible injection mark at both sides intragluteal. Follow-up on 24-Oct-07: The patient received the second dose of Gardasil o

Other Meds:

Lab Data:

History: Dental surgery

Prex Illness:

Prex Vax Illns:

Vaers Id: 305606-3 (D) Related reports: 305606-1; 305606-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	01-Apr-2008		02-Jun-2008	03-Jun-2008	--	WAES0805USA04734	04-Jun-2008

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

Symptom Text: Information has been received from a physician concerning a "17 year old" female who on an unspecified date was vaccinated with GARDASIL. In April 2008, approximately 6 weeks ago the patient died. The physician reported that one of the patient's mother did not want to agree to the vaccine because her friend's daughter died after receiving it. The 17 year old patient was found dead on the floor by her mother. The autopsy was performed and the outcome was unspecified. The physician only has information on the patient that refused the vaccine. No further information was provided. The reporter felt that the event was disabling and life threatening. 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 All comb. w/AND

Vaers Id: 309233-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Apr-2007	22-Jun-2007	56	10-Apr-2008	11-Apr-2008	--	WAES0804USA00429	27-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0384U	1	Left arm	Unknown	
HEPA	MERCK & CO. INC.	0250U	1	Left arm	Unknown	

Seriousness: DIED, HOSPITALIZED, SERIOUS

MedDRA PT Arrhythmia, Brain death, Brugada syndrome, Convulsion, Death, Electrocardiogram QT prolonged, Headache, Life support, Rash

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter with a history of seizures and heart arrhythmias, who on 25-JAN-2007 was vaccinated with a first dose of Gardasil. On 27-APRIL-2007 the patient was vaccinated with a second dose of Gardasil. Concomitant therapy included LAMICTAL, vitamins (unspecified) and KEPPRA. Subsequently, the patient began to have seizures, developed a rash on her arm, and was complaining about headaches. On 22-JUN-2007 the patient experienced a heart arrhythmia and was hospitalized. Due to the arrhythmia the patient was placed on life support and died on 29-JUN-2007. The patient's mother reported that the patient had an electrocardiogram (EKG) about 5 years ago to test for prolonged QT syndrome. The test came back normal. It was reported that at that time the patient was in and out of the emergency room due to having seizures periodically. The patient had been seeing a neurologist and had not had any seizures for about two years until she received the second dose of Gardasil. The patient's mother reported after her daughter's death and burial she had received copies of her daughter's medical records. Throughout the reports it showed that for the past five years the patient had prolonged QT syndrome, and proguda syndrome "which causes seizures and heart arrythmias." The patient's cause of death was prolonged QT syndrome, brain death, and proguda syndrome. No product quality complaint was involved. The seizures, rash, headaches, heart arrythmias, prolonged QT syndrome, brain death, and proguda syndrome were considered to be other important medical events. Additional information is not available.

Other Meds: LAMICTAL; KEPPRA; vitamins (unspecified)

Lab Data: electrocardiogram

History: Convulsion; Arrhythmia

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 All comb. w/AND

Vaers Id: 310262-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Apr-2008	05-Apr-2008	4	21-Apr-2008	22-Apr-2008	NC	WAES0804USA02336	25-Apr-2008

VAX Detail:

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

Seriousness: DIED, ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician concerning a 20 year old female with no medical history reported, who on 01-APR-2008 was vaccinated with a dose of Gardasil. On 05-APR-2008, the patient died four days after receiving Gardasil. The patient sought unspecified medical attention. An autopsy was performed which ruled out suicide and anything suspicious. The cause of death is currently unknown and they are performing toxicology tests to try to determine the cause. No product quality complaint was involved. The reportable physician considered death to be immediately life-threatening and disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: autopsy, 04/??/08, ruled out suicide or anything suspicious; diagnostic laboratory, 04/??/08, toxicology results unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 314524-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	01-Apr-2008		02-Jun-2008	03-Jun-2008	--	WAES0805USA04734	03-Jun-2008

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

Symptom Text: Information has been received from a physician concerning a "17 year old" female who on an unspecified date was vaccinated with GARDASIL. In April 2008, approximately 6 weeks ago the patient died. The physician reported that one of the patient's mother did not want to agree to the vaccine because her friend's daughter died after receiving it. The 17 year old patient was found dead on the floor by her mother. The autopsy was performed and the outcome was unspecified. The physician only has information on the patient that refused the vaccine. No further information was provided. The reporter felt that the event was disabling and life threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316983-1 (D) **Related reports:** 316983-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-May-2008	12-Jun-2008	15	23-Jun-2008	24-Jun-2008	NH		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	0	Left arm	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Convulsion, Cyanosis, Death, Mydriasis, Pallor, Pulmonary oedema, Pupil fixed, Unresponsive to stimuli, Urinary incontinence

Symptom Text: Death 9/9/08 Death certificate states COD as idiopathic seizure disorder. 8/5/08 Reviewed ER medical records of 6/12/2008. Records reveal patient found unresponsive, prone on her bed when parent went to awake for school. Last seen at bedtime. Pupils fixed & dilated, cyanotic & pale, incontinent of urine, developed pulmonary edema during resuscitation. Unable to resuscitate.

Other Meds:

Lab Data:

History: Seizures PMH: 'problems w/alcohol'.

Prex Illness:

Prex Vax Illns:

Vaers Id: 317695-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
42.0	F	12-Apr-2008	14-Apr-2008	2	27-Jun-2008	30-Jun-2008	FR	WAES0806MYS00011	30-Jun-2008

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

Seriousness: DIED, SERIOUS

MedDRA PT Abdominal pain, Death, Haemorrhage, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a health professional concerning a 42 year old female who on 12 Apr 2008 was vaccinated with GARDASIL. Prior to the vaccination, the patient was reported looking weak and lost weight. On 14 Apr 2008, the patient returned to the clinic and complained of abdominal pain and bleeding. The patient was treated with painkillers for abdominal pain and advised to return if pain persists. The patient never came back. The second dose was due on 12 Jun 2008 but the patient did not turn up. On 14 Jun 2008, the clinic was informed that the patient had died. The cause of death was unknown. The reporter felt that abdominal pain, bleeding and death 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:

Vaers Id: 317757-1 (D) **Related reports:** 317757-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Jun-2008	15-Jun-2008	2	27-Jun-2008	30-Jun-2008	IN		10-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1447U	0	Left arm	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Arrhythmia, Cardiomegaly, Cardiomyopathy, Cyanosis, Death, Left ventricular hypertrophy, Muscle rigidity, Obesity, Pulmonary oedema, Splenomegaly, Unresponsive to stimuli

Symptom Text: Death -coroner says enlarged heart & enlarge spleen 7/4/08 Reviewed PCP medical records of 1999-6/2008 which included vax record. In 8/2007, c/o of tiredness & loss of appetite. Monospot (-). On day of vax, patient was well, weight noted as 237, otherwise no complaints. 7/8/08 Autopsy report states COD as arrhythmia due to cardiomyopathy.States anatomic findings of obesity, pulmonary edema, mild & left ventricular hypertrophy w/myocardial nuclear enlargement. Patient had been found non-responsive by family. EMS found patient cyanotic w/rigor & no further resuscitation was performed. Family reported patient had been well earlier in the evening. Albuterol inhaler was found at scene but no suspicious features at scene.

Other Meds: none

Lab Data: toxicology and other test came back negative expect trace amount of nicotine (father heavy smoker)

History: overweight PMH: recurrent colds/sore throat, neg strep.

Prex Illness: none

Prex Vax Illns:

Vaers Id: 318244-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		07-Jul-2008	08-Jul-2008	FR	WAES0806USA09042	08-Jul-2008

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, Malaise, Pulmonary embolism

Symptom Text: Information has been received from a physician concerning a 20 year old female with no relevant medical history reported who was vaccinated with a first dose of GARDASIL on an unspecified date. Subsequently, exact onset not reported, the patient felt unwell. About 6 weeks post vaccination, she experienced pulmonary embolism with fatal outcome. An autopsy is scheduled. Other business partner numbers included: E2008-05832. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 318491-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Jul-2008	09-Jul-2008	--	WAES0806USA08737	09-Jul-2008

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

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Death, Hypersensitivity

Symptom Text: Information has been received from a physician who was told by a patient's mother that a female patient with a sulfa allergy who on an unspecified date was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported), which was well tolerated. On an unspecified date, the patient was vaccinated with a second dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient died. The cause of death was reported as allergic reaction to GARDASIL. The physician stated that the patient who died was not her patient and she knew no further details. Follow-up information was received from the physician who reported that a other of one of her patients had said to her, that she "thought" she read this report on the internet. The physician asked the patient's mother to find out where she read the report. The patient's mother could not find the report and did not know where to locate the source information. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: 319533-1 (D) **Related reports:** 319533-2; 319533-3; 319533-4; 319533-5; 319533-6; 319533-7

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Jun-2008	20-Jun-2008	17	17-Jul-2008	18-Jul-2008	MD		05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0053X	2	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Cardiac arrest, Death, Heart rate irregular, Physical examination normal, Pulmonary oedema, Spleen disorder, Splenomegaly, Supraventricular extrasystoles

Symptom Text: Pt received her 3rd and final dose of HPV vaccine on 6/3/08. Per mother patient was found dead, in bed on 6/22/08, in her dorm room at an out-of-state college. According to the autopsy the patient had been dead for about 48 hours. According to mother autopsy was negative except for splenic inflammation. 8/22/08 Autopsy report also states Final Diagnoses: Cardiac arrest, cause undetermined w/recent history of PAC w/otherwise normal EKG; normal echocardiogram 2/08; no evidence of myocarditis; acute pulmonary edema; slight splenomegaly; cardiac blood neg for ethanol; urine (+) for ethanol=16 mg/dl; liver (+) for acetaldehyde (incidental finding). 3/5/09-records received for DOS 8/22/07-seen for routine visit and first annual pap test..PE normal. First HPV vaccine administered. 2/4/09-records received for DOS 11/20/07-C/O chronic PAC and irregular heart beat.

Other Meds: none

Lab Data: none - apparently healthy young woman 8/22/08-records received-cardiac blood neg for ethanol; urine (+) for ethanol=16 mg/dl; liver (+) for acetaldehyde (incidental finding). 3/5/09-records received-pap smear normal. 2/4/09-records recei

History: reported allergy to penicillin and cephid 3/5/09-records received-Allergic to penicillin.

Prex Illness: none

Prex Vax Illns:

Vaers Id: 319810-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Aug-2007	20-Sep-2007	45	21-Jul-2008	22-Jul-2008	IL	WAES0807USA02139	29-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0012U	2	Unknown	Unknown	

Seriousness: DIED, ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Cardiac arrest, Convulsion, Death, Fall, Mydriasis, Pulmonary congestion, Pulmonary oedema, Pulse absent, Pupil fixed, Respiration abnormal, Syncope, Unresponsive to stimuli, Ventricular fibrillation, Visceral congestion

Symptom Text: Information has been received from a certified medical assistant concerning a 14 year old female who was vaccinated with a first dose of GARDASIL and experienced syncope. She was taken to an emergency room and released. The patient was vaccinated with a second dose of GARDASIL (unspecified time). Subsequently, the patient experienced her first seizure (unspecified time) and was taken to the emergency room (no further details provided). The patient was vaccinated with a third dose of GARDASIL at 15 years old. Approximately 27-JUN-2008, two weeks after the third dose, the patient developed a complication. She was taken to the hospital by ambulance but passed away during the transport from an unknown cause. The physician has asked the mother for the autopsy report. The reporting medical assistant considered the syncope, seizure and "a complication" were considered to be immediately life-threatening and disabling. Additional information has been requested. 2/13/09 Autopsy report received. COD: Seizure Disorder. Summary Diagnoses: Clinical history of seizure disorder. Pulmonary congestion and edema. Passive visceral congestion. 2/20/2009 ER received from CDC. Pt presented to ER via EMS following witnessed seizure activity with fall from standing. Upon EMS arrival pt had agonal respirations and was pulseless in V-fib at 650. Upon arrival in ER unresponsive, pupils fixed and dilated, no cardiac activity. Resuscitation unsuccessful and pt expired.

Other Meds: Unknown

Lab Data: Unknown. Labs and Diagnostics: Tox screen (-).

History: Unknown. PMH: 1 prior seizure 8/2007. 4/28/09 Additional records received from PCP at CDC's request. Pt in for OV 1/30/07 with c/o allergy sx and requesting HPV#1-given 0012U. Returned 3/22/07 for HPV#2-given 1427F with Boostrix AC52B012AA. Mild URI 4/25/07. OV 6/12/07 in F/U to ER visit for seizure on 6/11/07. Syncope noted. Sent for tests. OV 6/28/07 Echo and blood work repor

Prex Illness:

Prex Vax Illns:

Vaers Id: 320559-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		28-Jul-2008	29-Jul-2008	--	WAES0806USA08705	29-Jul-2008

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: Initial and follow up information has been received from a physician, who was told by one of his patients, that the mother of a consumer was told by a neurologist that there were 4,400 kids who have died following vaccination with GARDASIL. No product quality complaint was involved. Attempts are being made to verify the existence of patients. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 320909-1 (D)

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-2008	01-Aug-2008	--	WAES0807USA04740	01-Aug-2008

VAX Detail:

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

Seriousness: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death, Fatigue, Injection site pain, Viral infection

Symptom Text: Information has been received from a physician concerning a 22 year old female who on an unspecified date was vaccinated with her third dose of GARDASIL. Subsequently the patient experienced soreness at the injection site and fatigue. The outcome of soreness at the injection site and fatigue was not reported. Two months after receiving her third dose of GARDASIL, the patient died. The cause of death was "viral insult to the heart". Unspecified medical attention was sought. Follow-up information was received via telephone call from the physician. The patient was a family member. She did not have the vaccination dates or lot numbers since she did not give them. The physician reported that the patient's mother thought that the patient died related to GARDASIL. She did not have the cause of death. The physician refused to provide patient information, information was gave to the coroner. The physician considered "viral insult to the heart" to be immediately life-threatening and disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 320910-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		31-Jul-2008	01-Aug-2008	--	WAES0807USA04504	01-Aug-2008

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 Death

Symptom Text: Information has been received from a physician concerning his patient's daughter who on an unspecified date was vaccinated with a dose of GARDASIL. The patient's mother told to the physician that her daughter died in her dorm room 4 days after receiving the dose. The physician did not have much information because he did not administer the vaccine and the patient's daughter was not his patient. The reporter did not know the name of the physician who administered the vaccine. The physician considered the event to be life threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 321405-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		06-Aug-2008	07-Aug-2008	--	WAES0808USA00030	07-Aug-2008

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 at least three different offices concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient died. One office mentioned that it had something to do with spleen, another office said that the case was closed; the patient died of natural causes, and a third office said that this case was still under investigation. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321696-1 (D)** **Related reports:** 321696-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Mar-2008	03-Apr-2008	3	08-Aug-2008	11-Aug-2008	MO		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Left arm	Intramuscular	

Seriousness: DIED, HOSPITALIZED, SERIOUS

MedDRA PT Arrhythmia, Brain oedema, Cardiac arrest, Convulsion, Cough, Death, Dyspnoea, Fall, Haemorrhage, Headache, Hypotonia, Lobar pneumonia, Loss of consciousness, Organ donor, Respiratory tract congestion, Syncope, Tongue biting, Tremor, Upper respiratory tract congestion

Symptom Text: To Whom It May Concern: My daughter went to our nurse practitioner at Health Care Center on March 31, 2008 for a sore throat. She complained of her throat for about two days prior. Pt would get pharyngitis and strep about twice a year since she was 13. She received a shot of ROCEPHIN in the office on March 31st as well she was given a prescription for ZITHROMAX (Z-PAK) at the same time. I'm not sure exactly what time her appointment was it was around 11:00 am. that day. She dropped off her prescription at the pharmacy and I picked up on my way home. She took her first dose of ZITHROMAX on the 31st. She stayed home from school the next two days. She slept late both days which is not abnormal for her. In the evenings we played rummy, she was congested and coughing a little. She complained of a headache the next night and I gave her some ibuprofen. On Wednesday April 3rd she went to school, (school gets out at 3:05 p.m.) after school she went to tract practice. Her tract practice was a short one, I know she ran but I'm not sure how much. She stopped at a convenience store on the way home from school and got a Red Bull. She went home and changed clothes for work. She called me between 4:30 and 5:00 p.m. on her way to work to tell me about the road being blocked due to rain where we live. She parked her car and was walking the short distance into where she works she collapsed and started seizing. A lady in the drive through told the owner that she had fallen and he went out immediately. He said she was shaking, the employees inside called 911 and then me. The owner told me she stopped shaking and took a few strained breaths and then went limp. The police officer arrive within three minutes, he was a first responder. He did not check for a pulse or attempt CPR (I am in the process of getting a police report as well). Just as I got there an off duty paramedic arrived and started CPR. It took quite awhile before the ambulance arrived; she had been down too long. I later learned that they did not get her heart started unt

Other Meds: 3/31 ROCEPHIN; 3/31 ZITHROMAX

Lab Data: lab work, Cat scans, X-rays

History: Hx of pharyngitis; Bacterial Meningitis at 17 mons

Prex Illness: Sore throat

Prex Vax Illns:

Vaers Id: 322250-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		15-Aug-2008	18-Aug-2008	--	WAES0808USA01968	18-Aug-2008

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 registered nurse (R.N.) concerning a 22 year old female (a relative of another employee) who was vaccinated with a third dose of GARDASIL. Subsequently the patient died. The cause of death was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 323430-1 (D) **Related reports:** 323430-2; 323430-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	13-Jul-2007	01-Apr-2008	263	27-Aug-2008	28-Aug-2008	UT	WAES0808USA03969	20-Nov-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0522U	0	Right arm	Intramuscular	
TDAP	UNKNOWN MANUFACTURER	C2734AA	0	Left arm	Intramuscular	
HEPA	SMITHKLINE BEECHAM	AHAVB143AA	0	Right arm	Intramuscular	

Seriousness: DIED, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Amyotrophic lateral sclerosis, Asthenia, Ataxia, Axonal neuropathy, Blood product transfusion, Constipation, Cough, Dehydration, Depression, Dysarthria, Dysphagia, Dysphonia, Dyspnoea, Dysstasia, Facial paresis, Fatigue, Gastrointestinal tube insertion, Guillain-Barre syndrome, Headache, Intensive care, Motor dysfunction, Motor neurone disease, Muscle contractions involuntary, Muscular weakness, Musculoskeletal pain, Nausea, Neck pain, Nervous system disorder, Neurological examination abnormal, Neuromyopathy, Oral intake reduced, Pneumonia aspiration, Progressive bulbar palsy, Respiratory failure, Tachycardia

Symptom Text: Information has been received from a neurologist concerning a 21 year old female previously in good health who in March 2008, was vaccinated with the first dose of GARDASIL (lot# not provided). Concomitant medication included several other vaccinations (not including MENACTRA). Subsequently, the patient developed motor neuron disease consistent with amyotrophic lateral sclerosis (ALS). Her progressive clinical course began in April 2008. The patient had not received a second dose of GARDASIL or any other vaccines since onset of symptoms. She developed upper extremity weakness which had become generalized and much more severe. She had been hospitalized in intensive care for several weeks with respiratory failure. Her condition deteriorated despite treatment with immunoglobulin. She had upper and lower motor neuron features with fasciculations. There is no sensory loss. Diagnostic workup included cerebrospinal fluid analysis (CSF) and muscle biopsy that ruled out other conditions (such as Guillaine Barre) and clinical picture is consistent with amyotrophic lateral sclerosis. Antineuronal antibodies were pending. A Superoxide dismutase (SOD) was pending and Stathmin (SMN) test will be ordered if SOD was normal. The reporting physician did not believe that illness was related to GARDASIL. Additional information has been requested. This is one of several reports from the same source. 9/9/08 Autopsy states COD as unclassified neurologic process, clinically presumed to be atypical GBS vs bulbar varient of ALS. FINAL DX 8/17-8/21/08 admission: amyotrophic lateral sclerosis & death by respiratory collapse. Developed cough, difficulty breathing, difficulty swallowing, poor oral intake, constipation, lack of energy 6 days prior to admit; had received Depo-Provera & outpatient IVIG prior to admit w/o any improvement. Admitted to ICU. Gradually worsened over the hospital stay, had NGT for feeding but refused PEG tube placement or tracheostomy. Referred to hospice & expired. FINAL DX 7/28-8/1/2008 admission: axona

Other Meds: therapy unspecified

Lab Data: None LABS: EMG/NCS abnormal. Brain MRI abnormal; c-spine MRI WNL. CSF WNL. West Nile IgG (+), IgM (-)but testing done s/p IVIG. ANA (+). Echocardiogram WNL, SPI-C MRI. Muscle biopsy (+) marked neurogenic changes. CXR (+) for possibl

History: None 11/28/2007 - Received Twinrix, IM, RA, lot# AHABB100AA PMH: purpura fulminans age 5 or 8 s/p chickenpox. Pulmonary HTN in childhood. Underweight at birth & Nissen surgery w/G-tube as newborn for 1st year of life, repair of pectus excavatum age 17. Oral contraceptives, hypothyroidism. Allergic sulfa. Family hx of seizures

Prex Illness:

Prex Vax Illns:

Vaers Id: **324002-1 (D)** **Related reports:** 324002-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Feb-2008	12-Mar-2008	15	03-Sep-2008	04-Sep-2008	OH		05-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Right arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Circulatory collapse, Dehydration, Diabetic ketoacidosis, Pulmonary embolism, Sudden death

Symptom Text: Sudden death occured on 3/12/2008. 9/4/08-records received-Cause of Death:cardiovascular collapse as a consequence of pulmonary emboli, dehydration and diabetic ketacidosis.

Other Meds: none

Lab Data: Full Autopsy done. Immediate cause of death was massive pulmonary embolus. Secondary was Type 1 Diabetes (previously undiagnosed). Vitreous Humor glucose was 767 9/4/08-records received- Vitreous glucose 767.

History: none

Prex Illness: none noted

Prex Vax Illns:

Vaers Id: 325063-1 (D) **Related reports:** 325063-2; 325063-3; 325063-4; 325063-5

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	15-Sep-2008	16-Sep-2008	KS	WAES0809USA00837	03-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1740U	0	Unknown	Unknown	

Seriousness: DIED, ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Asthenia, Azotaemia, Cardiac failure congestive, Cardiomyopathy, Chest pain, Chills, Death, Dizziness, Dyspnoea, Hypotension, Hypoxia, Intensive care, Intra-aortic balloon placement, Malaise, Myocardial infarction, Myocarditis infectious, Pain, Pyrexia, Respiratory distress, Shock, Tachycardia, Ventricular tachycardia, Viral cardiomyopathy, Viral myocarditis

Symptom Text: Information has been received from a physician concerning a 17 year old female with acne who on 24-JUL-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included erythromycin, solution, topical. On 04-AUG-2008, the patient experienced abdominal pain, chest pain and aching everywhere and was hospitalized. On 05-AUG-2008, the patient experienced myocarditis and died. Diagnosis was myocarditis but the doctor said it was not related to GARDASIL. The last time she was seen in this office was 2005. No additional information at this time. Additional information has been requested. 10/01/08 Death certificate states COD as myocarditis & CHF as contributing factor. 9/22/08 Reviewed PCP medical records. Reveals patient experienced abdominal pain, chest pain & aching everywhere. Expired 8/5/08 w/viral infection of the heart. Concomitant med was erythomycin topical solution for acne. Patient noted to be in good health on day of vaccination. 4/2/09 Received hospital medical records for 8/3-8/4/2008. FINAL DX: deceased secondary to severe nonischemic cardiomyopathy secondary to viral myocarditis Records reveal patient experienced fever, chills, feeling unwell x 2-4 days. Presented to ER w/abdominal & chest pain, weakness, dizziness, hypotensive, tachycardia, SOB, respiratory distress w/hypoxemia, azotemia, shocklike symptoms. EKG w/diffuse ST changes & ST elevations. Dx w/acute anteroseptal MI Emergent cardiac cath revealed EF 23% & balloon pump placed. Intensive care, deteriorated, V-tach, decompensation, extensive resuscitation efforts failed.

Other Meds: erythromycin

Lab Data: Unknown LABS: WBC 10.3(H). Troponin greater than 100(H) & CPK 5492(H), CKMB 313.1(H) c/w infectious myocarditis, possibly viral. TSH 0.09(L). CRP 38.3(H). BNP 533(H). ANA neg. ASO 200(+). CXR abnormal w/water bottle appearing hea

History:

Prex Illness: Acne

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 334611-1 (D) **Related reports:** 334611-2; 334611-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	26-Nov-2008	08-Dec-2008	12	10-Dec-2008	10-Dec-2008	IL		04-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLUN	MEDIMMUNE VACCINES, INC.	500569P		Unknown	Unknown	
MNQ	SANOFI PASTEUR	U2730AA		Right arm	Unknown	
HPV4	MERCK & CO. INC.	0070X	2	Left arm	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Cold sweat, Death, Dizziness, Headache, Malaise, Nausea, Urinary incontinence

Symptom Text: Patient, a previously healthy 19 year-old female college freshman died suddenly yesterday, approximately 10 days after receiving Gardasil & menningococcal vaccines. Vaccines were administered by a medical provider in her hometown while she was home for the Thanksgiving holiday, sometime around 11-28-08. She had a medical appointment pending for 12-8-08 (the day of her death) with the Student Health Service; medical clerk had entered "possible seizure" as the reason for making the appointment. Patient had no history of epilepsy. She complained of a headache and not feeling well in the 24 hours prior to her death. She went to bed at 10:30 PM on 12-7-08, in her dorm room with a roomate. She appeared to still be sleeping the next morning when her roomate left for class. Her body was discovered still in bed around 5 PM that day (12-8-08) with rigor mortis. No history of substance abuse, alcohol intake, or depression or other mental health issues. She was a happy, achieving student. This report is filed by a friend of patient's parents, who is a physician (board certified internal medicine & geriatrics). Report also filed online today with the FDA. Patient's mother can be reached at home for additional details. Memorial service & funeral 12-12-08 and 12-13-08. Only known past medical history requiring physician attention was facial acne. 12/10/2008 Recived records from health center via CDC. Seen 11/3/08 with c/o sore throat, cough, muscle aches and nasal d/c. PE (+) for pharyngeal erythema, purulent nasal drainage, nasal turbinate changes, and lymphadenopathy. Assessment: Probable viral URI with ? sinusitis. Tx: Biaxin. Received from CDC via email: The patient had no previous health problems. She was a freshman and was seen at the college health clinic only once on 11/3/08 for sinusitis. She was on Yaz birth control pills and a topical acne medication. After the death, police questioned her roommate who said that the pt did go out on the evening of 12/6/08 and had a few alcoholic drinks, but not an excessive a

Other Meds: None known. ?? oral contraceptive or an antibiotic for acne.

Lab Data: Autopsy performed 12-9-08 was unrevealing per family verbal report to me; no signs of intracranial bleed, meningitis, cardiomyopathy, trauma. Toxicology report still pending at this time. Post-mortem tox screen (-).

History: Acne. PMH: PCN allergy. Acne. On OCs (Yaz). 12/10/2008 Recived records from health center via CDC. Seen 11/3/08 with c/o sore throat, cough, muscle aches and nasal d/c. PE (+) for pharyngeal erythema, purulent nasal drainage, nasal turbinate changes, and lymphadenopathy. Assessment: Probable viral URI with ? sinusitis. Tx: Biaxin.

Prex Illness: None.

Prex Vax Illns:

Vaers Id: 335270-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-Apr-2008	16-Jul-2008	86	15-Dec-2008	16-Dec-2008	FR	WAES0812USA02421	16-Dec-2008

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

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Death, Headache, No reaction on previous exposure to drug, Pain, Ruptured cerebral aneurysm

Symptom Text: Information has been received from a general practitioner concerning an 18 year old female with pollen allergy, allergic asthma and who was overweight, with a family history of the mother having multiple sclerosis, who on 12-MAR-2008 was vaccinated with the first dose of GARDASIL, lot # not reported, which was well tolerated. It was reported that the second dose of GARDASIL, lot # not reported, was given intramuscularly (IM) to the right deltoid on 21-APR-2008. Concomitant therapy included SERETIDE, albuterol, NASACORT and KESTINE. There was no contraceptive use. On 16-JUL-2008 the patient experienced sudden brutal cephalgia and then she suffered from a pain evocating an aneurysm during rupture. The patient suddenly died in spite of resuscitation technique performed by the agency which evoked a ruptured aneurysm. An autopsy was on-going and the results would be provided. As to the reporter there may not be any link between adverse effect and vaccination. The reported cause of death by the ageny was ruptured cerebral aneurysm, but it had not been confirmed yet by the results of the autopsy which were still pending. Additional information has been requested. Other business partner numbers include E2008-11575.

Other Meds: KESTINE; NASACORT; SERETIDE; albuterol

Lab Data: Unknown

History:

Prex Illness: Pollen allergy; Allergic asthma; Overweight

Prex Vax Illns:

Vaers Id: 337242-1 (D)

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		14-Jan-2009	15-Jan-2009	NM		29-Jan-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 Autopsy, Death

Symptom Text: My daughter had her 3rd GARDASIL vaccine in Sept. She was a very healthy young lady, she went to take a shower and died. Autopsy report states undermined death. There was no sign of trauma to the body to indicate a fall. She had pointed the shower head away from her and she got down on her knees and put her head on the edge of the tub and passed away. This has been a living nightmare for her family. She is not the only one to have had problems and death from this vaccine. Please I beg you to please take it off until it can be further tested. -not tested long enough to begin with- There will be others that will die if the cause is not found. 1/29/09-records received-COD-undetermined.

Other Meds:

Lab Data:

History: No medical problems-- no allergies -- No drug use, alcohol or smoking. Had all her medical check ups!!!

Prex Illness:

Prex Vax Illns:

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

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Jan-2007	31-Aug-2007	240	21-Jan-2009	22-Jan-2009	NM		08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0955F	0	Left arm	Intramuscular	FLU HPV4

Seriousness: DIED, SERIOUS

MedDRA PT Abnormal behaviour, Autopsy, Death, Dermatitis contact, Fatigue, Headache, Hypersomnia, Menorrhagia, Menstrual disorder, Metrorrhagia, Muscle spasms, Nasal congestion, Oropharyngeal pain

Symptom Text: Headaches, periods were very erratic. She would have them every 14 days @times, and others just spotting. Very bad cramps and periods were heavier after the 1st Gardasil shot. Wasn't her normal spunky and happy self. She was very tired and the last few weeks before she passed away, sheslept alot during the day which she never did. Never had any other problems prior to the Gardasil shots. She recieved all three shots in the series. Last shot was 5-2-2007. 2/9/09-autopsy report received-COD-undetermined by autospy and toxicology.3/18/09-records received-well visit C/O contact dermatitis, nasal congestion, itchy sore throat times 2-3days. HPV4 lot#1424 F received 1/3/07 in right deltoid. Lot #0384U received 5/2/07 left deltoid and 12/2/08 lot#0955F left deltoid.

Other Meds: Nasonex (Pseudovent 400 substituted for Entex 400 120 capsule),Claritan, Triamcinolene Acetonide cream for rash on wrist.

Lab Data: 4/7/09-path report received-multiple tissues with extensive autolysis and bacterial overgrowth. Molecular evidence of a Clostridium sp.

History: Seasonal allergies. None other.

Prex Illness: Went in for sinisitus, and had a sore throat. She had bad sinus allergies. But they still gave her the shots.

Prex Vax Illns: none~ ()~~0~Patient|none~ ()~~0~Sibling

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 338452-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Oct-2008	30-Dec-2008	71	28-Jan-2009	29-Jan-2009	FR	WAES0901USA03040	29-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1316U	1	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Death

Symptom Text: Information has been received from a health authority (reference # PEI2009000661) concerning a 15 year old female who on 20-OCT-2008 was vaccinated with the first dose of GARDASIL, lot #1427U (batch #NH15200) IM into the left upper arm. No information regarding toleration was given. On 29-DEC-2008, the patient was vaccinated with a second dose of GARDASIL, lot #1316U (batch #NH45640) IM into the left upper arm. On 30-DEC-2008 the patient died. According to the preliminary report, the autopsy showed no acute or chronic organic disease. The possibility of carbon monoxide intoxication was not yet ruled out. Investigation by public prosecution is ongoing. Lot checks have been requested. Other business partner numbers included: E2009-00404. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 338561-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Dec-2008	01-Jan-2009	5	29-Jan-2009	30-Jan-2009	FR	WAES0901USA03398	30-Jan-2009

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

Seriousness: DIED, HOSPITALIZED, SERIOUS

MedDRA PT Arrhythmia, Atrial fibrillation, Autopsy, Cyanosis, Death, Dyspnoea, Hyperthermia, Hypothermia, Intensive care, Leukocytosis, Lung disorder, Malaise, Multi-organ failure, Mydriasis, Tachycardia, Tremor, Ventricular hypokinesia

Symptom Text: Information has been received from a specialist and from the health authority, concerning a 20 year old female with asthenia, anxiety/overwork syndrome and psychologic fragility since May 2008 and a history of cardiac murmur during childhood, who in OCT-2008 was vaccinated with the first dose of GARDASIL. The patient had no adverse effects after this dose. Concomitant therapy included BUSPAR, LEXOMIL, magnesium (unspecified) (+) pyridoxine hydrochloride and hormonal contraceptives (unspecified). On 27-DEC-2008 the patient was vaccinated with the second dose of GARDASIL, batch number not reported. It was reported that 3 days after the second dose of GARDASIL, i.e. in JAN-2009 the patient presented with hyperthermia at 38 C associated with breathlessness. After a malaise during shopping on 01-JAN-2009 the patient consulted her general practitioner; she had tremor and tachycardia. Blood analysis was performed on 03-JAN-2009 and revealed a slight hyperleukocytosis (12.4 103/mm3). By the evening on 03-JAN-2009 the patient presented with a malaise again but with no dyspnea and after taking BUSPAR. 2 hours later the intervention of EMUR (emergency medical mobile unit) could lead to recuperate a sinusal rhythm. Continuous arrhythmia with atrial fibrillation was diagnosed. The patient was transferred to medical intensive care service: she presented with bilateral mydriasis, hypothermia at 33.7 C, the result of measure of sugar in her blood was increased at 3.18 and she had cyanosis of face, ears, and extremities. Radiological examinations revealed a pneumopathy of the right middle pulmonary lobe and septal hypokinesia with paradoxical septal. There was no cocaine and no benzodiazepines. The patient presented with multiorgan failure under high dose of amines and then she dies in spite of the cardiopulmonary by-pass and extra corporeal oxygenation assistance. An autopsy was performed (unspecified date) and found no cause of death, also reported as information on autopsy was still awaited. Other business partner numbers incl

Other Meds: BUSPAR; LEXOMIL; hormonal contraceptives (unspecified); magnesium (unspecified) (+) pyridoxine hydrochloride

Lab Data: electrocardiogram, 03Jan09, arrhythmia with atrial fibrillation; X-ray, 03Jan09, pneumopathy of right middle pulmonary lobe and septal hypokinesia; body temp, 01?Jan09, 38 C; WBC count, 03Jan09, 12.4.103/mm3; body temp, 03Jan09, 33.7 C; blo

History: Cardiac Murmur

Prex Illness: Asthenia; Anxiety; Overwork; Psychological disorder NOS

Prex Vax Illns:

Vaers Id: 339771-1 (D) **Related reports:** 339771-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Apr-2008	26-Oct-2008	181	18-Feb-2009	19-Feb-2009	IL		08-May-2009

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

Seriousness: DIED, SERIOUS

MedDRA PT Cardiac arrest, Cardiomegaly, Cough, Pulmonary embolism, Upper respiratory tract congestion

Symptom Text: She developed a pulmonary embolism after having 3 rounds of vaccine GARDASIL. She was a healthy, active teenager. 2/23/09-autopsy report received immediate cause:Massive pulmonary embolism. Mild cardiomegaly. Last several days C/O cough and congestion. 3/9/09-ED records received for DOS 10/26/08-presented in full cardiac arrest after suffering a full and prolonged cardiac arrest, aystole. Expired.

Other Meds:

Lab Data: 3/9/09-records received-WBC 17.3.

History: 5/7/09-records received-5/7/09-records received-office visit 4/21/00-evaluation for dehydration, vomiting, sore throat and febrile. Impression strep pharyngitis. 9/2/05-routine physical. Assessment:overweight. Office visit 1/4/08-C/O lump in neck noticed in 9/07. Intermittently hurts. Assessment:mild lymphadenopathy.

Prex Illness:

Prex Vax Illns: Bloodclot~HPV (Gardasil)~3~13~Patient

Vaers Id: 341030-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		04-Mar-2009	05-Mar-2009	FR	WAES0902CAN00119	05-Mar-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 an Agency concerning a 14 year old female who was vaccinated with GARDASIL, lot # not available. Subsequently the patient died. The cause of death was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 343612-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Nov-2008	26-Nov-2008	25	07-Apr-2009	08-Apr-2009	FR	WAES0903AUS00084	08-Apr-2009

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

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Hypertrophic cardiomyopathy, Sudden death

Symptom Text: Information has been received from a physician, via agency, as part of a business agreement (manufacturer control No. GARD 2009 03 27 LS2), concerning a 23 year old female who in November 2008 was vaccinated with GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified) in the form of a vaginal contraceptive ring. On 26-NOV-2008, a few days after vaccination with GARDASIL the patient died suddenly. The cause of death was attributed to hypertrophic cardiomyopathy. It was reported that an autopsy was performed (report not provided). A few days prior to her death, the patient had visited her physician to discuss contraception. She was not taking any other drugs other than contraception and had no underlying conditions or hereditary conditions. The reporter considered that hypertrophic cardiomyopathy was not related to therapy with GARDASIL, stating "I'm sure it was not directly related". Additional information has been requested.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History:

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: 343777-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	U	Unknown	Unknown		09-Apr-2009	10-Apr-2009	VA	WAES0904USA00201	10-Apr-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 an 11 year old patient who was vaccinated with GARDASIL (lot number, route and site not reported). Subsequently the patient died. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 344385-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		20-Apr-2009	21-Apr-2009	CA	WAES0904USA02014	21-Apr-2009

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

Symptom Text: Information has been received from an office manager that the physician heard from the physician's colleague that a 16 year old female colleague's patient was given an unspecified dose of GARDASIL (Lot not reported) on a Friday and on Monday the patient passed away (specific dates were unknown). The reporter considered the event as disabling and life threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 345435-1 (D)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		01-May-2009	04-May-2009	--	WAES0904USA03499	04-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 via the internet concerning a 21 year old female who was vaccinated with GARDASIL. The patient died 4 days after vaccination. The cause of death was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns: