

# VAERS Line List Report

Report run on: 07 SEP 2007 12:15

**Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND**

**Vaers Id:** 287888-1 (D)

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

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	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:**

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**Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND**

**Vaers Id:** 282372-1 (D)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
17.0	F	01-Jun-2007	01-Jun-2007	0	20-Jun-2007	21-Jun-2007	FR	WAES0706USA02451	21-Jun-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	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:**

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**Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND**

**Vaers Id:** 280163-1 (D)

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

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	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:**

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**Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND**

**Vaers Id:** 279592-1 (D)

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

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	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:**

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Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND

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

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	12-Mar-2007	26-Mar-2007	14	12-Jun-2007	13-Jun-2007	--	WAES0705USA05011	05-Jul-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	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, 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:**

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**Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND**

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

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
19.0	F	12-Mar-2007	26-Mar-2007	14	02-Apr-2007	03-Apr-2007	CA		05-Jul-2007

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

**Seriousness:** DIED, SERIOUS

**MedDRA PT** Cor pulmonale, Coronary artery thrombosis, Echocardiogram abnormal, Pulmonary congestion, Pulmonary embolism, Pulmonary oedema, Sudden cardiac death, Thrombosis

**Symptom Text:** Given Gardasil vaccine dose #1 3/12/07. No adverse reaction reported. Collapsed and died on 3/26/07 secondary emboli (records unavailable). 4/3/07 T/C to coroners bureau to request prelim COD. Spoke w/investigating deputy who stated autopsy done at Medical Center. T/C to physician at Medical Center who is actually a cardiologist, not pathologist, who had responded to the code & pronounced. Spoke w/secretary who states from Death Certificate COD is sudden cardiac death and pulmonary embolism. Echocardiogram revealed very enlarged right ventricle & small left ventricle as well as large blood clots within both the right atrium & right ventricle. Letter faxed to pathology department to request final autopsy report. 6/25/07 Received Autopsy Report which reveals following anatomic diagnosis: 1. Pulmonary embolism, occlusive a. pulmonary trunk, left hilar & peripheral vessels b. acute cor pulmonale (by echocardiogram) 2. Pulmonary congestion & edema, bilatera a. no evidence of anomalous coronary artery distribution b. no evidence of ventricular dysplasia

**Other Meds:**

**Lab Data:**

**History:** None

**Prex Illness:** None

**Prex Vax Illns:**

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**Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND**

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

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
12.0	F	01-Mar-2007	07-Mar-2007	6	02-Apr-2007	03-Apr-2007	NY		30-Aug-2007

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

**Seriousness:** DIED, SERIOUS

**MedDRA PT** Abdominal pain, Autopsy, Cardiomegaly, Chest X-ray abnormal, Cough, Gastroenteritis, Mitral valve incompetence, Myocarditis, Nervousness, Palpitations, Pyrexia, Rhinorrhoea, Ventricular tachycardia, Viral myocarditis

**Symptom Text:** presented to ED with Ventricular tachycardia. Preliminary autopsy finding of myocarditis. 4/3/07 Spoke w/ME who stated prelim COD as acute myocarditis, presumably viral. States patient had PMH of heart murmur which was evaluated by ped cardiologist who found mild aortic & mitral valve insufficiency & regurgitation. ME states did not see evidence of that on autopsy but did find cardiomegaly. Also states patient had been taken to ER on day of death for abdominal pain w/fever & was dx w/gastroenteritis. CXR at that time revealed cardiomegaly. No EKG or cultures were done. Was d/c to home & continued to not feel well. Parent found patient in bathroom unresponsive at approx 2AM & was transported to a second ER where she expired. ME states patient had approx 2 week hx of cough & runny nose prior to death. 6/12/07 Received final Autopsy Report which reveals COD as acute probable viral etiology myocarditis & manner of death as natural. 6/29/07 Received ER records from hospital where patient expired which reveal patient was in respiratory arrest & had been intubated by EMS. ACLS measures were unsuccessful & patient pronounced. 8/24/07 Received cardiology consult which reveals patient evaluated for heart murmur in 2005 which had been diagnosed for long time but never evaluated. Patient admitted to palpitations & nervousness. Patient history did not reveal any evidence of rheumatic fever. Antibiotic endocarditis prophylaxis recommended prior to dental & surgical procedures. Patient was to f/u w/cardiology in 2-3 years to document progress of valvular insufficiency. FINAL Cardiology DX: Aortic & mitral valve insufficiency of unknown etiology.

**Other Meds:**

**Lab Data:** ER LABS of 3/8/07: ABG pH 7.23, po2 62. Serum glucose 353, Creat 1.7, albumin 2.6, total protein 4.9, SGPT 62, SGOT 359. Blood c/s was neg. 2005 Cardiology LABS: echocardiogram revealed mild mitral valve & aortic valve insufficiency. Mi

**History:** aortic and mitral valve insufficiency, unknown aetiology

**Prex Illness:** none

**Prex Vax Illns:**

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**Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND**

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

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

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	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

Report run on: 07 SEP 2007 12:15

**Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND**

**Vaers Id:** 278865-1 (D)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
15.0	F	02-Mar-2007	01-Mar-2007	-1	17-May-2007	18-May-2007	AZ		16-Jul-2007

<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>	<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>
	HPV4	MERCK & CO. INC.	1424F	1	Left arm	Intramuscular	HPV4 TDAP

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

**MedDRA PT** Acute respiratory distress syndrome, Chest pain, Cough, Cough, Influenza, Mechanical ventilation, Multi-organ failure, Myalgia, Nasal congestion, Pharyngolaryngeal pain, Pneumonia staphylococcal, Pyrexia, Respiratory failure, Rhinorrhoea, Sepsis, Staphylococcal infection

**Symptom Text:** Onset of symptoms on 3/1/07: fever, sore throat, cough, and myalgia. Respiratory failure on 3/6/07. 6/1/07 Received Death Certificate from epidemiologist which reveals COD as multiorgan system failure and influenza B viral sepsis with contributing cause of staphylococcal secondary infection. Medical records included w/death certificate indicate patient was transferred to higher level of care on 3/6, was intubated & in PICU w/pneumonia & ARDS. Reportedly had been in good health until 3/1/07 when she developed sore throat, nasal congestion, rhinorrhea & low grade fever. Continued to worsen & developed myalgias, chest pain & nonproductive cough w/higher fever. Seen by PCP on 3/5 & rapid strep was neg & dx was probable influenza. Sent home & developed nausea, vomiting & diarrhea as well as petechial rash over abdomen. Taken to outlying ER on 3/6 & found to be in respiratory failure, intubated & transferred to higher level of care. Respiratory status declined further & was placed on oscillator & ECMO. Peds ID consult done. Consult states had HPV vax at PCP on 3/2 & no other recent vaccines. 6/1/07 Received fax medical & vaccine records from CDC who had contacted provider. Reveals that on 1/2/07, patient received TDaP & HPV. On 3/2/07 received HPV #2. VAERS database updated w/same. On day of vax patient also dx w/right CTS, migraine HA, scoliosis. She was referred to Neuro & PT for the CTS & HA.

**Other Meds:** Topamax

**Lab Data:** Influenza B isolated by viral culture. Specimen sent to CDC for antigenic characterization. LABS: Throat & urine c/s neg. Blood & endotracheal c/s + for MRSA. Nasal swab + for influ B virus. Lymph node c/s were neg. from PCP office, St

**History:** PMH: migraine headaches. Family HX: younger sister also w/strep neg sore throat. Letter from school that group A strep infections present.

**Prex Illness:**

**Prex Vax Illns:**

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**Vax Name: HPV (GARDASIL) , HPV (NO BRAND NAME) (Comb. w/OR) Reported Date: 10-MAY-07 - 07-SEP-07 All comb. w/AND**

**Vaers Id:** 282747-1 (D)

<u>Age</u>	<u>Gender</u>	<u>Vaccine Date</u>	<u>Onset Date</u>	<u>Days</u>	<u>Received Date</u>	<u>Status Date</u>	<u>State</u>	<u>Mfr Report Id</u>	<u>Last Edit Date</u>
Unknown	U	Unknown	Unknown		25-Jun-2007	26-Jun-2007	--	WAES0706USA02351	26-Jun-2007
<u>VAX Detail:</u>	<u>Type</u>	<u>Manufacturer</u>		<u>Lot</u>	<u>Prev Doses</u>	<u>Site</u>	<u>Route</u>	<u>Other Vaccine</u>	
	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:**