

Report run on: 04 NOV 2009 10:32

VAERS Line List Report

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Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 361353-1 (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>
9.0	F	08-Oct-2009	14-Oct-2009	6	16-Oct-2009	19-Oct-2009	CA		28-Oct-2009

<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>
	FLU	SANOFI PASTEUR	U3203AA	2	Left arm	Intramuscular	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500751P	0	Unknown	Unknown	

Seriousness: DIED, SERIOUSMedDRA PT Apnoea, Cardiac arrest, Chills, Death, Lividity, Lung consolidation, Mydriasis, Pallor, Pupil fixed, Resuscitation

Symptom Text: None Stated. On 10/19/09, the PCP stated that coroner called him and told him that he found consolidation of the lungs on autopsy. Autopsy report is not complete yet. 10/20/09 ER records received service date 10/14/09. Assessment: Cardiac arrest. CPR initiated. Pupils fixed and dilated. Apnea, pale. Rigor, lividity. 10/22/09 PCP /Nursing medical records received, service dates 11/11/03 to 10/14/09. Assessment: Death. Office staff unable to contact patient's family, eventually visited patient's home. learned that patient was found dead at home and taken to ER.

Other Meds: None

Lab Data: CBC: 2.5, 7.5, 21.3, 207; Sed rate 125. 10/20/09 ER records received service date 10/14/09. LABS and Diagnostics: EEG - Asystole. CHEM - Glucose 107 mg/dL (H) Calcium 3.5 mg/dL (L) Albumin 3.4 g/dL (L) Alk Phos 170 U/L (L). CBC - WBC 2.5

History: H/O Leukemia 2002; Down's Syndrome. 10/22/09 PCP /Nursing medical records received, service dates 11/11/03 to 10/14/09. Down Syndrome. Cough, fever. Frequent colds. Discharge from eyes. Vomiting and diarrhea. Lymphadenopathy. Foot pain. CBC abnormal.

Prex Illness: LimpingPrex Vax Illns:

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Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 362855-1 (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>
35.0	F	22-Oct-2009	25-Oct-2009	3	26-Oct-2009	27-Oct-2009	OR		02-Nov-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500765P	0	Unknown	Unknown	FLU

Seriousness: DIED, ER VISIT, HOSPITALIZED, SERIOUS**MedDRA PT**

Abdominal pain upper, Acidosis, Acute respiratory distress syndrome, Asplenia, Brain injury, Cardiac arrest, Chills, Cyanosis, Death, Diarrhoea, Dyspnoea, Electromechanical dissociation, Endotracheal intubation, Hyperhidrosis, Hypotension, Infection, Influenza like illness, Intensive care, Livedo reticularis, Lung infiltration, Nausea, Pulse absent, Renal disorder, Respiratory arrest, Resuscitation, Sepsis, Septic shock, Tachycardia, Tachypnoea, Vaginal haemorrhage, Vomiting

Symptom Text:

Patient got sick with flu like symptoms on 10/24 around 1PM, went to hospital with trouble breathing around 9PM, was pronounced deceased at 1AM on 10/25. 10/27/09 ER and hospital records received service date 10/25/09. Assessment: Death due to septic shock secondary to infection of unknown source. Asplenia. Patient had nausea, vomiting, chills, stomach cramping, diarrhea, tachypnea, hypotension, diaphoresis for one day. Limited oral intake. Became cyanotic around lips, fingernails, and toenails. Presented to ER hypotensive, hypoxic, no longer breathing. Tachycardia. Cardiac arrest presenting as pulseless electrical activity (PEA). Hyperacidemia. Resuscitation. Intubated and transported to ICU. Bilateral infiltrates consistent with acute respiratory distress syndrome. End-organ damage including kidneys and brain. Repeated PEA. No pulse. Mottling of head and extremities. Overwhelming sepsis and septic shock. Patient expired. 11/02/09: Primary Care Records received for date of service 10/9/09. Seasonal flu vaccine record received VAERS updated. Assessment: Presented with vaginal bleeding x 3 weeks, had hx. of D&C in 08 2/2 heavy vaginal bleeding. Also presented with a cold that started 5 days prior, afebrile at visit. Seasonal Flu vaccine given.

Other Meds:

none known

Lab Data:

/27/09 ER and hospital records received service date 10/25/09. LABS and DIAGNOSTICS: ECG - Abnormal, sinus tachycardia, Nonspecific ST and T wave abnormality. Arterial Blood gases: pCO2 50 mmHg (H) O2 Sat 83% (L) Bicarb 8.0 mmol/L (L) Base

History:

none. /27/09 ER and hospital records received service date 10/25/09. Splenectomy. Appendectomy. 11/02/09: Primary Care Records received for date of service 10/9/09. PMH: Hereditary spherocytosis with splenectomy, D&C, L ACL Repair, L arthroscopic knee surgery.

Prex Illness:

spherocytosis, hemolytic onemica

Prex Vax Illns:

VAERS Line List Report

Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 362855-1 (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>
35.0	F	22-Oct-2009	25-Oct-2009	3	26-Oct-2009	27-Oct-2009	OR		02-Nov-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500765P	0	Unknown	Unknown	FLU

Seriousness: DIED, ER VISIT, HOSPITALIZED, SERIOUS**MedDRA PT** Abdominal pain upper, Acidosis, Acute respiratory distress syndrome, Asplenia, Brain injury, Cardiac arrest, Chills, Cyanosis, Death, Diarrhoea, Dyspnoea, Electromechanical dissociation, Endotracheal intubation, Hyperhidrosis, Hypotension, Infection, Influenza like illness, Intensive care, Livedo reticularis, Lung infiltration, Nausea, Pulse absent, Renal disorder, Respiratory arrest, Resuscitation, Sepsis, Septic shock, Tachycardia, Tachypnoea, Vaginal haemorrhage, Vomiting**Symptom Text:** Patient got sick with flu like symptoms on 10/24 around 1PM, went to hospital with trouble breathing around 9PM, was pronounced deceased at 1AM on 10/25. 10/27/09 ER and hospital records received service date 10/25/09. Assessment: Death due to septic shock secondary to infection of unknown source. Asplenia. Patient had nausea, vomiting, chills, stomach cramping, diarrhea, tachypnea, hypotension, diaphoresis for one day. Limited oral intake. Became cyanotic around lips, fingernails, and toenails. Presented to ER hypotensive, hypoxic, no longer breathing. Tachycardia. Cardiac arrest presenting as pulseless electrical activity (PEA). Hyperacidemia. Resuscitation. Intubated and transported to ICU. Bilateral infiltrates consistent with acute respiratory distress syndrome. End-organ damage including kidneys and brain. Repeated PEA. No pulse. Mottling of head and extremities. Overwhelming sepsis and septic shock. Patient expired. 11/02/09: Primary Care Records received for date of service 10/9/09. Seasonal flu vaccine record received VAERS updated. Assessment: Presented with vaginal bleeding x 3 weeks, had hx. of D&C in 08 2/2 heavy vaginal bleeding. Also presented with a cold that started 5 days prior, afebrile at visit. Seasonal Flu vaccine given.**Other Meds:** none known**Lab Data:** /27/09 ER and hospital records received service date 10/25/09. LABS and DIAGNOSTICS: ECG - Abnormal, sinus tachycardia, Nonspecific ST and T wave abnormality. Arterial Blood gases: pCO2 50 mmHg (H) O2 Sat 83% (L) Bicarb 8.0 mmol/L (L) Base**History:** none. /27/09 ER and hospital records received service date 10/25/09. Splenectomy. Appendectomy. 11/02/09: Primary Care Records received for date of service 10/9/09. PMH: Hereditary spherocytosis with splenectomy, D&C, L ACL Repair, L arthroscopic knee surgery.**Prex Illness:** spherocytosis, hemolytic onemica**Prex Vax Illns:**

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Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 361119-1 (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>
77.0	M	06-Oct-2009	08-Oct-2009	2	16-Oct-2009	19-Oct-2009	FR	2009020904	19-Oct-2009

<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>
	FLU(H1N1)	CSL LIMITED	NULL		Unknown	Intramuscular	

Seriousness: DIED, HOSPITALIZED, SERIOUS**MedDRA PT** Aneurysm, Back pain, Chest pain, Death

Symptom Text: Report received from a foreign regulator on 14-OCT-2009. A 77-year old male patient (initials unknown, date of birth: 16/4/1932) received PANVAX H1N1 (batch unknown) intramuscularly on 06-OCT-2009. The patient was taking concomitant atenolol (25 mg daily), Seretide accuhaler (250 mcg twice daily), Spiriva and Ventolin. Approximately 30 hours after vaccination on 08-OCT-2009, the patient had terrible back pain which continued through the night and then commenced chest pains. The patient was advised by the surgery to attend hospital immediately. The patient attended hospital, and died of an aneurysm on 08-OCT-2009. No autopsy results were provided. The regulatory assessed the causality as possible.

Other Meds: Atenolol, dosage 25 mg QD, oral; SERITIDE, dosage 250mg BID; SPIRIVA; VENTOLIN**Lab Data:****History:****Prex Illness:****Prex Vax Illns:**

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Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 361120-1 (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>
24.0	F	30-Sep-2009	01-Oct-2009	1	16-Oct-2009	19-Oct-2009	FR	2009020903	19-Oct-2009

<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>
	FLU(H1N1)	CSL LIMITED	NULL		Unknown	Intramuscular	

Seriousness: DIED, HOSPITALIZED, SERIOUS**MedDRA PT** Cardiac arrest, Death, Influenza like illness

Symptom Text: Report received from a foreign regulatory on 14-OCT-2009. A 24-year old female patient (initials and date of birth unknown) received PANVAX H1N1 (batch unknown) intramuscularly on 30-SEP-2009. The patient had a history of cerebral palsy, intellectual disability, epilepsy and foetal alcohol syndrome. On 01-OCT-2009, 1 day after PANVAX vaccination, the patient developed flu-like illness. On 02-OCT-2009, the patient developed a cardiac arrest and dies out of hospital. Apart from flu-like illness, pre-arrest clinical information was not known. Full results of a coronial enquiry are expected in 6-12 months. The regulator assessed the causality as possible, and noted the patient was admitted to hospital.

Other Meds:**Lab Data:****History:** cerebral palsy; intellectual disability; epilepsy; foetal alcohol syndrome**Prex Illness:****Prex Vax Illns:**

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Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 363458-1 (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>
46.0	F	26-Oct-2009	27-Oct-2009	1	28-Oct-2009	29-Oct-2009	FL		30-Oct-2009

<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>
	FLU(H1N1)	SANOFI PASTEUR	UP004AA	0	Unknown	Intramuscular	

Seriousness: DIED, SERIOUS**MedDRA PT** Asthenia, Death, Dizziness, Fatigue, Oropharyngeal pain, Postnasal drip, Weight decreased

Symptom Text: Client contacted Dr.'s office on 10/27/09 approximately equal to 0900 c/o feeling lightheaded and was not sure whether it was due to low BP or having received an H1N1 injection the day prior (10/26/09). Position: ESE Paraprofessional (worked with special needs children). An autopsy will be performed. 10/29/09 PCP medical records received service dates 10/26/09 to 10/28/09 includes vaccine records. Assessment: URI, low blood pressure, fatigue. On 10/27/09 Patient presents with low blood pressure and fatigue. Slight sore throat and post nasal drainage. Weak, 'woozy'. Weight loss of 38 lbs since 2/08. On 10/28/09 notified that patient had expired.

Other Meds: Metoprolol 50mg BID; HYZAAR 100mg/25mg QD; ASA 81 mg chew 1 QAM**Lab Data:**

History: Obesity; Hypertension; Hyperlipidemia etc. 10/29/09 PCP medical records received service dates 10/26/09 to 10/28/09 Hypertension, hyperlipidemia, pulmonary embolism, impaired fasting glucose, obesity, DVT, hydradenitis suppurative, skin grafting.

Prex Illness:**Prex Vax Illns:**

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Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 361877-1 (S)

<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>
66.0	F	02-Sep-2009	21-Sep-2009	19	20-Oct-2009	26-Oct-2009	TX		02-Nov-2009

<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>
	FLU(H1N1)	CSL LIMITED	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal distension, Acute respiratory distress syndrome, Arterial injury, Arterial repair, Arthralgia, Asthenia, Band neutrophil count increased, Bone marrow failure, Chest pain, Chills, Cough, Disseminated intravascular coagulation, Dyspnoea, Endotracheal intubation, Fasciotomy, Fatigue, Haemorrhage, Hypoxia, Myalgia, Oedema peripheral, Pain, Pancytopenia, Peripheral ischaemia, Pyrexia, Speech disorder, Unresponsive to stimuli, Vascular injury, Weight increased

Symptom Text: Patient received H1N1 Vaccine as part of a clinical trial on 9/2/09. She developed Myocarditis of unknown etiology with onset of symptoms 9/21/09. (See attached medical records). 10/28/09 Hospital records received service dates 9/24/09 to 10/7/09. Assessment: Non-ST segment elevation myocardial infarction Right profunda artery injury, right lower extremity ischemia. Patient with recent history of fevers, body aches, fatigue, nonproductive cough, chills, weight gain. Joint and muscle pain, weakness. Trouble talking. Transferred to a higher level facility. Bleeding from right groin. Patient developed shortness of breath. Chest pain. Fever. Became hypoxic with decreased responsiveness. Intubated. Pancytopenia. Abdomen distended. Bandemia and DCC. Edematous extremities. ARDS. Myelosuppression. Surgical procedures performed - repair of profunda artery on right side, four-compartment fasciotomy of right lower extremity. 10/28/09 ICD-9 Codes received: 786.06 Shortness of breath, 422.91 Idiopathic myocarditis, 323.9 Encephalitis, myelitis encephalomyelitis unspecified cause, 284.1 Pancytopenia, 790.6 Abnormal blood chemistry, 575.10 Cholecystitis unspecified.

Other Meds: Dapsone

Lab Data: See attached records. 10/28/09 Hospital records received service dates 9/24/09 to 10/7/09. LABS and DIAGNOSTICS: Troponins - 50.3 (H). Cardiac Catheterization - Abnormal, lateral myocarditis, mildly depressed left ventricular function. E

History: Asthma; Gastroesophageal reflux; "Skin condition". 10/28/09 Hospital records received service dates 9/24/09 to 10/7/09. Asthma, irritable bowel disease. Osteoporosis. GERD. Allergies - Penicillin, tetracycline. Surgeries - Rhinoplasty, cataracts, D&C, Tonsillectomy.

Prex Illness: None**Prex Vax Illns:**

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Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 362087-1 (S) **Related reports:** 362087-2

<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>
55.0	M	21-Oct-2009	21-Oct-2009	0	21-Oct-2009	22-Oct-2009	MI		26-Oct-2009

<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>
	FLU(H1N1)	SANOFI PASTEUR	UP002AA		Right arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS**MedDRA PT** Asthenia, Cyanosis, Dyspnoea, Heart rate increased, Immediate post-injection reaction, Malaise, Respiratory distress**Symptom Text:** Immediately after H1N1 vaccine IM administration Pt reported not feeling well, could not breathe, obvious respiratory distress, weakness, and cyanosis, elevated heart rate epinephrine auto injection given, 911 188/104 p.160, r 34, Pt. able to speak no LOC noted, EMS located very nearby, responded within approximately 5 minutes, Pt. was improving after epi, but when asked to sit upright by EMS unable to do so, became distressed again, Pt carried to stretcher by EMS, transported to Hospital via ambulance. 10/22/09 Medical record received for date 10/21/09 Lab value only:**Other Meds:****Lab Data:** Labs: HGB 13.4(L), HCT 38.3(L), RBC 4.29(L), alanine amino T 15(L).**History:** None Known**Prex Illness:** No**Prex Vax Illns:**

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VAERS Line List Report

Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 362196-1 (S)

<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>
1.5	F	16-Oct-2009	19-Oct-2009	3	22-Oct-2009	22-Oct-2009	UT		30-Oct-2009

<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>
	FLU(H1N1)	SANOFI PASTEUR	UP002AA	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS**MedDRA PT** Cough, Crying, Diarrhoea, Dyskinesia, Irritability, Malaise, Movement disorder, Muscle spasms, Muscle twitching, Pyrexia, Pyuria, Respiratory tract congestion, Rhinorrhoea, Screaming**Symptom Text:** Fever, irritability, seizure-like twitching, though no loss of consciousness, and no alteration in consciousness. Had normal CBC, electrolytes, CSF, normal CT of head, normal EEG, negative viral PCR panel. Pyuria (10 WBC - negative culture) Fever and twitching movements resolved after 3 days. 10/23/09 Hospital records received service dates 10/20/09 to 10/21/09. Assessment: Pyuria, resolving movement disorder with normal EEG. Patient presents with recent hx of mild febrile illness and seizure like activity. "Crabby and sick", runny bowel movement. Woke up screaming at midnight. Jerking of whole body, then screaming/crying for several minutes. Continued to have these events. Mild congestion, runny nose, cough. 10/29/09 Discharge summary received for DOS 10/20-10/22: Final DX: Spasms. Patient presented in ED with fever and spastic-like motions. Seizure concerns. Activity present during EEG. EEG and CT brain WNL. Discharged. Follow-up with PCP and possibly neuro as needed.**Other Meds:** none**Lab Data:** Electrolytes - normal CBC - normal CSF - normal Toxicology normal CT head - normal Cultures of CSF, blood and urine all negative Viral respiratory PCR panel - negative EEG - normal 10/23/09 Hospital records received service da**History:** None. 10/23/09 Hospital records received service dates 10/20/09 to 10/21/09. Induced delivery at 36 weeks. Phototherapy jaundice. Gastroesophageal reflux. Brief jerking of head with feeding. Rash around mouth.**Prex Illness:** No**Prex Vax Illns:**

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Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 362592-1 (S)

<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>
45.0	F	22-Oct-2009	22-Oct-2009	0	23-Oct-2009	28-Oct-2009	NY		28-Oct-2009

<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>
	FLU	SANOFI PASTEUR	UT3251BA	0	Left arm	Intramuscular	
	FLU(H1N1)	SANOFI PASTEUR	UP006AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Eye discharge, Ocular hyperaemia, Paraesthesia, Swelling face, Swollen tongue, Throat irritation

Symptom Text: Throat felt funny, face tingly, swollen, eyes very red and draining - tongue started to swell.

Other Meds: Zolofit; Lisinopril; Xanax

Lab Data: Unsure - treated at ER - per pt - IVs, IV BENADRYL, O2

History: Allergic BACTRIM, SULFA, Codeine, seasonal

Prex Illness: No

Prex Vax Illns:

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VAERS Line List Report

Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 362672-1 (S)

<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>
8.0	F	21-Oct-2009	22-Oct-2009	1	23-Oct-2009	27-Oct-2009	PA		02-Nov-2009

<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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	UP002AA		Unknown	Unknown	
	FLU	SANOFI PASTEUR	U3208AA		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Chills, Cough, Diarrhoea, Disorientation, Dyspnoea, Heart rate increased, Influenza, Lethargy, Mental status changes, Nasal congestion, Oropharyngeal pain, Pyrexia

Symptom Text: On 10/22/09 came to ER w/flu symptoms. Chills, increased HR, DB, lethargy and altered mental status. 10/29/2009 Dc summaryfor 10/22-10/25/2009. Patient with sx of cough, nasal congestion, fever, diarrhea, sore throat, disorientated and lethargic. PE was normal, for observation with neuro cks, rehydration. Tx: Flu A +, Tamiflu given. Dc Dx: altered mental status, Influenza A+, dehydration.

Other Meds:

Lab Data: Influenza A (+) Labs: CMP wnl, Dx tests: EKG wnl

History: PMH: Asthma, Eczema Allergies: NKDA

Prex Illness: Eczema

Prex Vax Illns:

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Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 362913-1 (S)

<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>
5.0	F	22-Oct-2009	23-Oct-2009	1	26-Oct-2009	27-Oct-2009	DC		28-Oct-2009

<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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Cough, Dysphonia, Pyrexia

Symptom Text: Hoarseness, cough, high fever

Other Meds:

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns:



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Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 363285-1 (S)

<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>
30.0	F	15-Oct-2009	18-Oct-2009	3	27-Oct-2009	29-Oct-2009	OH		02-Nov-2009

<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>
	FLU(H1N1)	UNKNOWN MANUFACTURER	500685P	0	Unknown	Unknown	FLU

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS**MedDRA PT** Chills, Cough, Dyspnoea, Gastroesophageal reflux disease, Hypokalaemia, Influenza, Malaise, Nasopharyngitis, Nausea, Pain, Pneumonia, Pyrexia, Tachycardia, Tachypnoea, Wheezing**Symptom Text:** Started with cold like sx on 10/18, continued with febrile, cough, tachypnic went to Urgent care on 10/20, given amoxicillin phenegan and mucinex, continued with fever, tachepnea, tachycardic, went to ER. Dx with Bi-Lateral Pneumonia and Hypokalemia. Swabbed for H1N1, send out test only. Given mulitple doses of IV Levaquin, IV and PO potassium, Tamiflu, other supportive medications. Per ER Doc and Hospitalist, presumed H1N1 positive, from the H1N1 vaccine given 3 days prior to the onset of symptoms. 10/28/09: Hospital Records and Discharge Summary received for Dates of Service 10/22/09 to 10/24/09. Final DX: Bilateral pneumonia with possible H1N1 influenza, GERD, Hypokalemia, improved. Assessment: Admitted 2/2 cough and SOB, 1 week after receiving flu mist vaccine. Experienced fever, cold, chills, body aches, wheezing, malaise and nausea. She went to an Urgent Care Center and was given Amoxicillin, but sx. continued to worsen. CXR with bilateral lung infiltrates. Placed on Tamiflu and IV Levaquin. Potassium supplementation given to correct hypokalemia. Discharged to home.**Other Meds:****Lab Data:** At this time, unknown blood cx results, unknown H1N1 official result. CXR revealed bilateral Pneumonia due to presumed H1N1 flu. 10/28/09: Hospital Records and Discharge Summary received for Dates of Service 10/22/09 to 10/24/09. Labs**History:** none. 10/28/09: Hospital Records and Discharge Summary received for Dates of Service 10/22/09 to 10/24/09. PMH: Hernia repair, C-Section, Tonsilectomy.**Prex Illness:** none**Prex Vax Illns:**

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Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 363299-1 (S)

<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	22-Oct-2009	26-Oct-2009	4	27-Oct-2009	28-Oct-2009	VT		03-Nov-2009

<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>
	FLU(H1N1)	NOVARTIS VACCINES AND DIAGNOSTICS	1008133P	0	Gluteous maxima	Intramuscular	FLU

Seriousness: HOSPITALIZED, SERIOUS**MedDRA PT** Drug exposure during pregnancy, Intra-uterine death, Nausea, Skin warm, Vomiting**Symptom Text:** 10/5/09 Seasonal flu vaccine. 10/14/09 Normal prenatal exam. 10/20/09 to 10/22/09 AM vomiting, "felt a little warm". 10/22/09 H1N1-afebrile. 10/26/09 Fetal demise at 30 5/7 weeks. 10/29/2009 hospital records for 10/26-/10/27/2009. patient at at 30 5/7 wks gestation, presented with c/o's decreased fetal movement, hx of nausea/vomiting x 2 days which resolved. Per doppler and ultrasound no FHR noted, no amniotic fluid around the baby noted. Tx: induced labor with Misoprostol/epidural anesthesia. Autopsy requested. DC DX Intrauterine Death Unspecified. ICD-9 Code 656.40**Other Meds:** Prenatal vitamins**Lab Data:** Ultrasound x 2 confirms diagnosis Labs: Antibody screen, VDRL neg, Hepatitis B and C negative, Chlamydia and Gonorrhea screening negative Dx studies: Doppler, US**History:** None-pregnancy PMH: none Allergies: NKDA**Prex Illness:** Patient denied**Prex Vax Illns:**

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Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 363592-1 (S)

<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>
8.0	M	16-Oct-2009	17-Oct-2009	1	29-Oct-2009	03-Nov-2009	GA		03-Nov-2009

<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>
	FLU(H1N1)	SANOFI PASTEUR	4P003AA	0	Left leg	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	500727P	0	Unknown	Unknown	
	MMR	MERCK & CO. INC.	0707Y	1	Left leg	Unknown	
	VARCEL	MERCK & CO. INC.	0727Y	1	Right leg	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Appendectomy, Vomiting

Symptom Text: Patient was having vomiting and abdominal pain within 24 hours post vaccines. Patient ended up having an appendectomy on 10.17.09.

Other Meds:

Lab Data: Seen at Hospital.

History: No

Prex Illness: No

Prex Vax Illns:

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Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 363685-1 (S)

<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>
52.0	F	26-Oct-2009	27-Oct-2009	1	29-Oct-2009	30-Oct-2009	PA		03-Nov-2009

<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>
	FLU(H1N1)	SANOFI PASTEUR	UP008AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Cerebral haemorrhage, Eye pain, Facial pain, Grand mal convulsion, Headache, Hypertension, Nausea, Nuclear magnetic resonance imaging brain abnormal, Speech disorder, Subarachnoid haemorrhage, Tinnitus, Toothache

Symptom Text: Developed Headache that progressively got worse with facial pain. 10/30/09 Medical records received DOS 10/28/09. HA x4 days radiating to right eye, face and teeth. Whistling in R ear. Nausea when severe. Neuro exam WNL except for slight speech articulation, improved with repetition. Brain MRI abnormal. Subdural hemorrhage with subarachnoid hemorrhage and intracerebral hemorrhage, , cephalgia, hypertension. Grand mal seizure witnessed after admit.

Other Meds:

Lab Data: Subarachnoid and subdural bleed. Labs & Diags: K 3.3 (L), CO2 97 (L), magnesium 1.3 (L), platelet count 144 (L), lymph 11.6 (L), monocytes 2.1 (L), Head CT - intracranial hemorrhage. Possible sinus thrombosis. CT angiography circle of wil

History: none. PMH: Hypertension, uterine fibroid. Family h/o of sudden cardiac death. Allergies: Macrobid.

Prex Illness: none

Prex Vax Illns:

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Vax Type: FLU(H1N1) All comb. w/AND

Vaers Id: 364197-1 (S)

<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>
1.3	M	17-Oct-2009	20-Oct-2009	3	01-Nov-2009	02-Nov-2009	WA		03-Nov-2009

<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>
	FLU(H1N1)	SANOFI PASTEUR	UP005AA		Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Intensive care, Mental status changes, Pyrexia

Symptom Text: Fever for 3 days followed by seizure/altered mental status requiring hospitalization. 10 days in hospital, including 5 days in PICU.

Other Meds: None

Lab Data: MRI confirmed ADEM

History: None

Prex Illness: No known illness at the time of vaccination

Prex Vax Illns:

VAERS Line List Report

Report run on: 04 NOV 2009 10:32

Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 360456-1 (S)

<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>
29.0	F	08-Oct-2009	10-Oct-2009	2	12-Oct-2009	12-Oct-2009	MN		30-Oct-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500756P	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS**MedDRA PT** Anxiety, Asthenia, Chest pain, Chills, Condition aggravated, Cough, Dizziness, Dyspnoea, Headache, Influenza like illness, Nausea, Painful respiration, Pharyngeal erythema, Productive cough, Pyrexia, Respiratory distress, Respiratory rate increased, Rhinorrhoea, Sinus disorder, Sputum discoloured, Steroid therapy, Tachycardia, Vomiting**Symptom Text:** Please note that this individual is a HCW. Developed fever, SOB, N/V with coughing, headache. Initial episode of ILI began on 10/1 (out from work until 10/8. Saw physician 1 week ago (10/5) for follow-up after having been on Prednisone, Albuterol and Codiene cough medication and received clearance to return to work. Stated since receiving the H1N1 FluMist vaccine on 10/8 her symptoms worsened. 10/13/09 ED/Outpatient Clinic records received service dates 9/30/09 to 10/11/09 Assessment: H1N1 Suspected. Patient presents with fever, productive cough, weakness, chills, shortness of breath, runny nose, sinus drainage, hurts to breath, headache, vomiting. Mild erythema pharynx. Respiratory distress, rapid respiratory rate, tachycardia. 10/13/09 PCP medical records from 9/15/09 to 9/30/09 hospital records 10/11/09 to 10/13/09. Assessment: Influenza like illness. Patient presents with anxiety, productive cough with yellow sputum, fatigue. Dizzy spells. Chest pain. Admitted for influenza like illness, respiratory distress and tachycardia. Shortness of breath with activity. Head pain. 10/29/2009 Discharge summary received for DOS 10/11-10/12. Final DX not provided. Brief discharge summary noting multiple treatment meds including prednisone, Duoneb, and Tamiflu. Patient to r/c in 5-10 days for follow-up**Other Meds:****Lab Data:** 10/13/09 ED/Outpatient Clinic records received service dates 9/30/09 to 10/11/09 10/13/09 PCP medical records from 9/15/09 to 9/30/09 hospital records 10/11/09 to 10/13/09. LABS and DIAGNOSTICS: Rapid FLU A/B Antigen (-). CBC - WNL. CHEM**History:** Employee neglected to share with vaccinator that she had been diagnosed with exercise induced asthma as a child. Screening tool was also used and this did not trigger acknowledgement of this history by the employee. 10/13/09 ED/Outpatient Clinic records received service dates 9/30/09 to 10/11/00. Postinfectious cough. Anxiety. Patient presented with runny nose, congestion, cough**Prex Illness:** HCW Employee had just ended a prescribed course of Prednisone on 10/5/09 and had recently been away from work (HCW) for approx.**Prex Vax Illns:**

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Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 360786-1 (S)

<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>
47.0	M	12-Oct-2009	12-Oct-2009	0	14-Oct-2009	14-Oct-2009	NC		21-Oct-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500754P	0	Unknown	Intramuscular	FLU

Seriousness: ER VISIT, LIFE THREATENING, SERIOUSMedDRA PT Allergy to vaccine, Hypersensitivity, Pharyngeal oedema, Swollen tongue

Symptom Text: Throat and tongue swelling. I was treated in the ER for allergic reaction. Received IV benadryl, solumedrol and Tagamet. Released after 2 and one half hours. 10/14/09 ED records received service date 10/12/09. Assessment: Allergic reaction to FluMist. Patient complained of throat swelling. Later said he felt better and was discharged.

Other Meds:Lab Data: 10/14/09 ED records received service date 10/12/09. LABS and DIAGNOSTICS: Puls Ox 100% Room Air.History: none. 10/14/09 ED records received service date 10/12/09. Occasional alcohol use.Prex Illness: no.Prex Vax Illns:

VAERS Line List Report

Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 361270-2 (S) Related reports: 361270-1

<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>
5.0	M	15-Oct-2009	15-Oct-2009	0	20-Oct-2009	22-Oct-2009	CT	500757PMEDIMMUNE	26-Oct-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500757	0	Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS**MedDRA PT** Condition aggravated, Cough, Croup infectious, Cyanosis, Dyspnoea, Stridor, Tachypnoea, Vomiting

Symptom Text: CROUP SOUNDING COUGH-WITHIN 3-5 MINUTES..HE COULD NOT BREATHE,OR EVEN TRIED CRYING-HE WAS NOT ABLE TO GET AIR IN HIS LUNGS..TURNED ON SHOWER FOR STEAM, BUT TOO LATE FOR ANY RELIEF..STARTED TURNING BLUE/GRAY.ALSO VOMITED GETTING INTO THE AMBULANCE...CALLED 911..HAD BEEN TAKEN BY AMBULANCE TO CLOSEST EMERGENCY FACILITY..IN ROUTE A MEDIC DID ADMINISTER A NEBULIZER TREATMENT-STARTED TO COME AROUND..DID HAVE 2 MORE TREATMENTS WHILE WE REMAINED AT THE CLINIC-ALSO DR. DID HAVE X-RAYS DONE TO CHECK FOR ANY OBSTRUCTION-NOTHING BUT SIGNS OF CROUP..WAITING FOR DR.S DECISION TO ADMIT HIM IN THE HOSPITAL OR DECIDE IF STABLE ENOUGH TO GO HOME...FINALLY WE WERE RELEASED TO GO HOME @ 6:00 AM FRIDAY MORNING TO FOLLOW-UP WITH OUR PEDIATRICIAN..PEDIATRICIAN DID PRESRIIBE A STERIOD MEDICATION FOR 3 DAYS FOLLOWING..RYAN STILL HAS A COUGH (NOT CROUP SOUNDING) AT THIS POINT IN TIME. 10/23/2009 records from PCP and ED visit date 10/15/2009 received. Patient presented post vaccination with c/o's croupy cough, difficulty breathing, loud stridor, vomiting and tachypnea. Tx'd with O2, racemic Epinephrine neb, and oral Decadron with resolution of sx. Dx: Acute Croup

Other Meds:**Lab Data:** XRAYS TAKEN @ CLINIC TO CHECK FOR OBSTRUCTIONS-N/A.. Lab : none Dx studies: CXR and Xrays of neck normal**History:** NO PMH: Otitis Media Allergies: Bactrim and Keflex 10/22/09 PCP records service dates 9/7/09 to 10/7/09. PMH: Clear fluid from nares. Dizziness secondary from epistaxis.**Prex Illness:** WOKE UP IN THE MORNING OF 10/15/09 W\SLIGHT COUGH-NO FEVER-SENT TO SCHOOL-WAS OK ALL DAY-SO I WENT AHEAD WITH THE VACCINE**Prex Vax Illns:**



VAERS Line List Report

Report run on: 04 NOV 2009 10:32

Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 361844-1 (S) **Related reports:** 361844-2

<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>
38.0	F	17-Oct-2009	17-Oct-2009	0	20-Oct-2009	26-Oct-2009	IA		28-Oct-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500763P		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS**MedDRA PT** Chest discomfort, Fatigue, Headache, Influenza serology negative, Pain, Pyrexia, Vomiting**Symptom Text:** Received intranasal vaccine-4 hrs later began to get a headache and chest discomfort as well as achy all over. Fever 102-103. Headache became severe. Aches all over, fatigued, vomiting. Has not been around ill people-no one in household ill. Her rapid test for Influenza was negative for A and B.**Other Meds:** CYMBALTA; LYRICA-stopped using; multivitamin**Lab Data:** WBC-3.7;blood c/s-negative; UA-clear; chloride 107**History:** Fibromyalgia; hx MVA; 3 C-sections**Prex Illness:** None**Prex Vax Illns:**

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Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 361844-2 (S) **Related reports:** 361844-1

<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>
38.0	F	16-Oct-2009	17-Oct-2009	1	23-Oct-2009	28-Oct-2009	IA		28-Oct-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500763P		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS**MedDRA PT** Cough, Dyspnoea, Ocular hyperaemia, Pyrexia**Symptom Text:** Fever 102 degrees, cough, shortness of breath & red eyes.**Other Meds:** CYMBALTA; Multivitamin**Lab Data:** Influenza A antigen - negative; Influenza B antigen - negative**History:** Fibromyalgia**Prex Illness:** none**Prex Vax Illns:**



VAERS Line List Report

Report run on: 04 NOV 2009 10:32

Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 362590-1 (S)

<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>
9.0	M	14-Oct-2009	21-Oct-2009	7	23-Oct-2009	28-Oct-2009	GA		29-Oct-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500761P	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS**MedDRA PT** Abasia, Blood creatine phosphokinase increased, Body temperature increased**Symptom Text:** Infection control nurse from hosp reported child admitted 10/22/09 temp 99.6, unable to walk, CPK - 3362. Reports 10/23 temp 99.3, CPK - 1165, moving all extremities (states she is unaware of ambulatory status).**Other Meds:****Lab Data:** See CPK results above.**History:** None known**Prex Illness:** None**Prex Vax Illns:**

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Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 362926-1 (S)

<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>
3.0	M	26-Oct-2009	26-Oct-2009	0	26-Oct-2009	27-Oct-2009	LA		03-Nov-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500759PCAA	1	Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUSMedDRA PT Cough, Eye rolling, Grand mal convulsion, Incontinence, Pruritus, RhinorrhoeaSymptom Text: Generalized Tonic-Clonic Seizure for 30 seconds. No treatment needed. Afebrile. No trauma. 10/28/2009 ED records from 10/26/2009. Patient with tonic-clonic seizure activity, eyes rolled back, incontinence, itching, runny nose and cough. Neuro exam WNL, no repeat seizure activity, no tx noted. DC DX New Onset Seizure ? related to H1N1 vaccine.Other Meds: NoneLab Data: CBC,CMP, UA, and Tox Screen were normal/negative. Labs: CBC, CMP, Tox screen, UA normalHistory: Reactive Airway Disease No history of Seizures NKDA PMH RAD Allergies: NKDAPrex Illness: NoPrex Vax Illns:



VAERS Line List Report

Report run on: 04 NOV 2009 10:32

Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 363268-1 (S)

<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>
7.0	M	22-Oct-2009	25-Oct-2009	3	27-Oct-2009	29-Oct-2009	OK		03-Nov-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500758P	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS**MedDRA PT** Abdominal pain, Ataxia, Back pain, Body temperature increased, Chills, Cough, Headache, Muscular weakness, Nausea, Pain in extremity, Pyrexia, Vomiting

Symptom Text: Pt. had bilateral lower extremity pain and weakness; he also had abdominal pain and low back pain. Tmax 103 degrees. 10/28/09: Hospital Record and Discharge Summary received for Dates of Service 10/25/09 to 10/27/09. Final DX: Ataxia, Bilateral lower extremity weakness and pain, Abdominal pain, rule out Guillain-Barre Syndrome. Assessment: Presented to the ED with fever of 103, chills, recent HA's, pain and weakness in the bilateral LE's, pain in the abdomen on the left and pain in the low back on the left. Also, one episode of nausea and vomiting as well as cough and headache. Decreased patellar reflex and difficulty walking. Patient discharged to home to follow up in 5 days. 10/29/09: Vaccine record received. No lot number included.

Other Meds: Multivitamin

Lab Data: Abdominal CT: mesenteric adenitis; CBC, 12.3; CRP, 6.32. 10/28/09: Hospital Record and Discharge Summary received for Dates of Service 10/25/09 to 10/27/09. Labs and Diagnostics: Rapid strep-Negative. CBC: WBC's 12.3 (H), Abs. Neut. 9.

History: None. 10/28/09: Hospital Record and Discharge Summary received for Dates of Service 10/25/09 to 10/27/09. PMH: Atopic dermatitis, circumcision.

Prex Illness: None**Prex Vax Illns:**



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Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 363419-1 (S)

<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>
5.0	F	20-Oct-2009	22-Oct-2009	2	28-Oct-2009	29-Oct-2009	WI		29-Oct-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	5007621	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS**MedDRA PT** Influenza like illness, Pain, Pyrexia, Rash, Urticaria**Symptom Text:** (REPORTED BY HOSPITAL) 104-105 FEVERS, BODY ACHES AND OTHER FLU LIKE SYMPTOMS. HIVE LIKE RASH TO FACE**Other Meds:****Lab Data:** RAPID INFLUENZA POSITIVE REPORTED THAT A COLLECTION WOULD BE SENT TO STATE LAB.**History:** NONE REPORTED**Prex Illness:** NONE**Prex Vax Illns:**



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Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 363629-1 (S)

<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>
34.0	F	21-Oct-2009	21-Oct-2009	0	29-Oct-2009	02-Nov-2009	VA		02-Nov-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500760P	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS**MedDRA PT** Blood pressure fluctuation, Chills, Dizziness, Heart rate increased, Sinus tachycardia, Tachycardia**Symptom Text:** Within 5 minutes of vaccine, experienced dizziness, chills, tachycardia/160 beats per minute and fluctuations in blood pressure. Within 6 hours, had elevated heart beat at rest and one other episode - approx. 6 hrs. after receiving vaccine of sinus tachycardia-170 bpm at rest and blood pressure spike-168/90 - normal around 100/60. Treated with BENADRYL, I.V. for hydration and beta-blocker to regulate heart and b.p. Continued heart rate & bp fluctuations 5 days out. Continued beta-blockers.**Other Meds:** ERRIN and SYNTHROID daily & prenatal vitamin**Lab Data:** EKG to assess heart rhythm speed; BP readings; Echocardiogram.**History:** Hypothyroidism; prior HELLP Syndrome during pregnancy (April 2008)**Prex Illness:** None**Prex Vax Illns:**

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Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 363708-1 (S)

<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>
2.0	M	26-Oct-2009	27-Oct-2009	1	29-Oct-2009	30-Oct-2009	OK		02-Nov-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	500759P	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUSMedDRA PT Bronchiolitis, DyspnoeaSymptom Text: Mom reported "heavy breathing at 8 pm 10/26/09 that continued next day. Took child to ER at Hospital where he was admitted with dx of bronchiolitis.Other Meds:Lab Data:History: nonePrex Illness: noPrex Vax Illns:

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Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 364070-1 (S)

<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>
40.0	M	27-Oct-2009	28-Oct-2009	1	30-Oct-2009	02-Nov-2009	PR		03-Nov-2009
<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>	
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.		500759P	1	Unknown	Unknown		

Seriousness: ER VISIT, HOSPITALIZED, SERIOUSMedDRA PT Asthenia, Chills, Malaise, PyrexiaSymptom Text: Patient developed sudden onset of high grade fever(103F),chills,weakness and malaise.Other Meds:Lab Data:History: Patient has a history of Chronic Malabsortion Syndrome and Immunoglobulin deficiency. He is receiving monthly Ig infuesions at home.Prex Illness:Prex Vax Illns:

VAERS Line List Report

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Vax Type: FLUN(H1N1) All comb. w/AND

Vaers Id: 364219-1 (S)

<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>
44.0	M	28-Oct-2009	29-Oct-2009	1	01-Nov-2009	02-Nov-2009	MI	H1N1NasalFlumist	03-Nov-2009

<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>
	FLUN(H1N1)	MEDIMMUNE VACCINES, INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS**MedDRA PT** Condition aggravated, Convulsion, Road traffic accident**Symptom Text:** Had A Seizure while driving...had not had a seizure during the day for 8 years Hit a light post with my car and damaged vehicle driving at approx. 25 MPH 11/2/09: Hospital records received for dates of stay 10/29/09 to 10/30/09. Dx: Breakthrough Seizure Disorder, History of Seizure, Motor Vehicle Accident. Assessment: Epileptic patient maintained seizure free on Tegretol x 8 years, received H1N1 vaccine and had a seizure while driving his car the following day. Accident was at low speed and pt. was unhurt. Monitored in the hospital overnight and discharged to home. Keppra started BID.**Other Meds:** Carbamazepine**Lab Data:** All Blood Work Showed my levels were good. Kept in hospital overnight for observation. Had no other side effects except a headache. 11/2/09: Hospital records received for dates of stay 10/29/09 to 10/30/09. Labs and Diagnostics: CBC and**History:** Epilepsy - Due to Head Trauma Taking Carbamazepine. 11/2/09: Hospital records received for dates of stay 10/29/09 to 10/30/09. PMH: Seizure disorder**Prex Illness:** NONE**Prex Vax Illns:**